Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3012033	2020-07-30	1	No/ 2020-07-30 (1)	Withdrawal of Consent by Participant/ SUBJECT REFUSED TO WAIT FOR VACCINATION. LEFT SITE PRIOR TO BEING VACCINATED.			
US3022215	2020-08-20	2	No/ 2020-09-30 (42)	Withdrawal of Consent by Participant/ SUBJECT STATES THAT SHE DOESN'T WANT TO PARTICIPATE ANYMORE.		No/ 2020-09-30 (42)	Withdrawal of Consent by Participant/ SUBJECT STATES THAT SHE DOESN'T WANT TO PARTICIPATE IN STUDY ANYMORE.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3082013	2020-08-10	1	No/ 2020-08-10 (1)	Other/ SUBJECT DID NOT MEET INCLUSION #7		No/ 2020-08-10 (1)	Other/ PARTICIPANT DID NOT MEET INCLUSION CRITERIA #7
US3102050	2020-07-29	1	No/ 2020-07-29 (1)	Withdrawal of Consent by Participant/ PARTICIPANT DECIDED NOT TO RECEIVE TREATMENT DESPITE ALREADY BEING RANDOMIZED.			

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3112118	2020-08-05	1	No/ 2020-08-05 (1)	Withdrawal of Consent by Participant/ SUBJECT DECIDED AFTER BEING RANDOMIZED NOT TO PARTICIPATE DUE TO LENGTH OF TRIAL. COULD NOT COMMIT TO 2 YEARS. SUBJECT DID NOT RECEIVE IP DRUG DOSING		No/ 2020-08-05 (1)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT. STATED LENGTH OF STUDY WAS TOO LONG AND COULD NOT COMMIT. SUBJECT DID NOT RECEIVE IP DOSING
US3172054	2020-08-11	1	No/ 2020-08-12 (1)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT			

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172068	2020-08-12	1	No/ 2020-09-03 (23)	Withdrawal of Consent by Participant/ NO LONGER INTERESTED			
US3172449	2020-10-21	2	No/ 2020-10-21 (1)	Withdrawal of Consent by Participant/ SUBJECT NEVER RETURNED TO COMPLETE VISIT.			

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202340	2020-08-26	3	No/ 2020-08-26 (1)	Other/ SUBJECT RANDOMIZED IN ERROR, DIDNâ€™T MEET I/E CRITERIA, NEVER DOSED		No/ 2020-08-26 (1)	Other/ SUBJECT RANDOMIZED IN ERROR, DIDNâ€™T MEET I/E CRITERIA, NEVER DOSED

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3212343	2020-09-02	3	No/ 2020-09-03 (2)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT ON 03SEP2020 DUE TO UNFORESEEN PERSONAL CIRCUMSTANCES, EVERY ATTEMPT WAS MADE BY SITE STAFF TO KEEP THE SUBJECT IN THE STUDY HOWEVER SHE DOES NOT WISH TO CONTINUE FURTHER.		No/ 2020-09-03 (2)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT ON 03SEP2020 DUE TO UNFORESEEN PERSONAL CIRCUMSTANCES, EVERY ATTEMPT WAS MADE BY SITE STAFF TO KEEP THE SUBJECT IN THE STUDY HOWEVER SHE DOES NOT WISH TO CONTINUE FURTHER.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222129	2020-08-13	2	No/ 2020-08-13 (1)	Other/ NO DIARY AVAILABLE DAY OF SCREEN WAS HELD ON VACCINATION BUT NEVER RETURNED FOR CONTINUATION IN TRIAL.			
US3252148	2020-08-12	2	No/ 2020-08-12 (1)	Withdrawal of Consent by Participant/ PATIENT JUST DID NOT WANT TO BE IN THE STUDY ANYMORE			

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3252359	2020-08-28	3	No/ 2020-08-28 (1)	Other/ AS PER PI PATIENTS BLOOD PRESSURE WAS TOO HIGH AFTER RANDOMIZATION TOOK PLACE. AS PER PI THE PATIENT DID NOT CONTINUE TO DOSING.		No/ 2020-08-28 (1)	Physician Decision/ AS PER PI PATIENTS BLOOD PRESSURE WAS TOO HIGH AFTER RANDOMIZATION TOOK PLACE. AS PER PI THE PATIENT DID NOT CONTINUE TO DOSING.
US3322268	2020-09-08	3	No/ 2020-09-11 (1)	Withdrawal of Consent by Participant/ PATIENT NO LONGER INTERESTED IN PARTICIPATING		No/ 2020-09-11 (1)	Withdrawal of Consent by Participant/ PATIENT NO LONGER INTERESTED IN PARTICIPATING

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3322391	2020-09-23	3	No/ 2020-09-24 (1)	Withdrawal of Consent by Participant/ VISIT 2 IP HELD PER PATIENT'S REQUEST; CONSENT WITHDRAWN		No/ 2020-09-24 (1)	Withdrawal of Consent by Participant/ VISIT 2 IP HELD PER PATIENT'S REQUEST; CONSENT WITHDRAWN
US3322423	2020-10-12	4	No/ 2020-10-23 (12)	Other/ SUBJECT RANDOMIZED IN ERROR, ENROLLMENT HAD CLOSED, NEVER DOSED		No/ 2020-10-23 (12)	Other/ SUBJECT RANDOMIZED IN ERROR, ENROLLMENT HAD CLOSED, NEVER DOSED

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3412093	2020-08-01	1	No/ 2020-08-06 (1)	Other/ SUBJECT WAS RANDOMIZED BUT DID NOT DOSE. THEREFOR THE SUBJECT DID NOT CONTINUE ON IN THE STUDY PER HIS DECISION SINCE HE WAS NOT DOSED AT THE FIRST VISIT.		No/ 2020-08-06 (1)	Other/ SUBJECT WAS UNABLE TO STAY FOR DOSING AND THEREFOR LEFT THE SITE PRIOR TO RECEIVING THE INJECTION. SUBJECT NEVER RETURNED TO THE SITE FOR HIS DOSING VISIT AND THEREFOR WAS RANDOMIZED BUT NOT DOSED.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3482315	2020-10-21	4	No/ 2020-10-21 (1)	Other/ PT WITHDRAWN BEFORE TREATMENT AFTER DISCUSSIONS WITH PPD ABOUT SUBJECT'S RACE (b) (6) -ENROLLMENT RESTRICTED TO MINORITIES		No/ 2020-10-21 (1)	Other/ PATIENT WAS ENROLLED BUT THEN WITHDRAWN AFTER DISCUSSIONS WITH PPD ABOUT THE SUBJECT'S RACE (b) (6) (b) (6)

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3522027	2020-08-06	1	No/ 2020-08-06 (1)	Other/ DUPLICATE OF US3522029		No/ 2020-08-06 (1)	Other/ THIS IS NOT A REAL PARTICIPAN
US3522153	2020-08-17	1	No/ 2020-08-27 (11)	Physician Decision/ SUBJECT WAS RANDOMIZED BEFORE BEING GIVEN IP. BLOOD PRESSURE WAS TOO LOW TO GIVE IP. SUBJECT WILL COME IN AT ANOTHER TIME AND WILL BE GIVEN NEW SUBJECT ID.		No/ 2020-08-27 (11)	Physician Decision/ SUBJECT WAS RANDOMIZED BEFORE BEING GIVEN IP. BLOOD PRESSURE WAS TOO LOW TO GIVE IP. SUBJECT WILL COME IN AT ANOTHER TIME AND WILL BE GIVEN NEW SUBJECT ID.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3522586	2020-09-04	3	No/ 2020-09-04 (1)	Withdrawal of Consent by Participant/ PT CONSENTED AT 1106, WITHDREW BEFORE BLOOD DRAW. PT PASSED OUT BEFORE BLOOD DRAW, AND WISHED TO BE REMOVED FROM THE STUDY.		No/ 2020-09-04 (1)	Withdrawal of Consent by Participant/ PARTICIPANT PASSED OUT AFTER TOURNIQUET PLACEMENT PRIOR TO BLOOD DRAW, WAS NO LONGER COMFORTABLE WITH CONTINUING.
US3672333	2020-08-26	2	ONGOING			No/ 2020-09-23 (29)	Adverse Event/ AE#1 AND DOSING DISCONTINUED DUE TO DAY 1 SWAB NEVER FOUND.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3702035	2020-09-15	3	No/ 2020-09-17 (1)	Withdrawal of Consent by Participant/ PARTICIPANT FELT TOO ANXIOUS TO CONTINUE WITH STUDY AND RECEIVE VACCINE ADMINISTRATION.		No/ 2020-09-17 (1)	Withdrawal of Consent by Participant/ PARTICIPANT FELT TOO ANXIOUS TO PROCEED WITH VACCINATION.
US3772025	2020-08-06	1	No/ 2020-11-05 (92)	Withdrawal of Consent by Participant/ SUBJECT W/C NOT DUE TO AN SAE/AE BUT DUE TO "NOT WANTING TO DEAL WITH THIS STUDY ANYMORE"		Yes/ 2020-09-09 (35)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3802101	2020-09-02	3	No/ 2020-09-02 (1)	Withdrawal of Consent by Participant/ SUBJECT RANDOMIZED IN ERROR, DIDNâ€™T MEET I/E CRITERIA, NEVER DOSED		No/ 2020-09-02 (1)	Withdrawal of Consent by Participant/ SUBJECT RANDOMIZED IN ERROR, DIDNâ€™T MEET I/E CRITERIA, NEVER DOSED

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\l16020101.sas 01DEC2020 04:35

Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3802222	2020-09-11	3	No/ 2020-09-11 (1)	Withdrawal of Consent by Participant/ W/D CONSENT BEFORE DOSING		No/ 2020-09-11 (1)	Withdrawal of Consent by Participant/ DUE TO RANDOMIZATION ERROR, SUBJECT WITHDREW CONSENT BEFORE DOSING. SUBJECT UNABLE TO COME FOR VISIT 2 IN WINDOW SO WITHDREW CONSENT

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3022208	2020-08-20	2	ONGOING			No/ 2020-09-10 (22)	Serious Adverse Event/ SAE #1
US3042166	2020-08-12	2	No/ 2020-10-20 (70)	Lost to Follow-Up		No/ 2020-09-18 (38)	Lost to Follow-Up
US3142173	2020-08-08	1	No/ 2020-10-30 (84)	Physician Decision/ PATIENT HAS BEEN NON COMPLIANT WITH VISITS AND INSTRUCTIONS. PATIENT HAS BEEN DISRUPTIVE AND VERBALLY ABUSIVE WITH STAFF MEMBERS.		Yes/ 2020-09-09 (33)	

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3152002	2020-07-27	1	No/ 2020-07-27 (1)	Other/ PATIENT HAD STRATIFICATION ERROR AFTER RANDOMIZATION AND HAD TO COME BACK TO BE RESCREENED UNDER US3152062.		No/ 2020-07-27 (1)	Other/ PATIENT HAD STRATIFICATION ERROR AFTER RANDOMIZATION AND HAD TO COME BACK AND BE RESCREENED UNDER A NEW NUMBER-US3152062.
US3162241	2020-09-16	3	No/ 2020-09-16 (1)	Other/ UNABLE TO COLLECT PROPER AMOUNT OF BLOOD FROM PATIENT.		No/ 2020-09-16 (1)	Other/ UNABLE TO COLLECT PROPER AMOUNT OF BLOOD FROM PATIENT.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172125	2020-08-14	2	No/ 2020-08-14 (1)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT			
US3172214	2020-08-19	2	No/ 2020-08-19 (1)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT			
US3172235	2020-08-20	1	No/ 2020-08-20 (1)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT			

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202365	2020-08-31	3	No/ 2020-08-31 (1)	Physician Decision/ RANDOMIZED IN ERROR -DID NOT RECEIVE ANY DOSES OF IP--NOT APPROPRIATE FOR PARTICIPATION PER INVESTIGATOR DURING EXAM--WAS INCOHERENT AND APPEARED TO BE UNDER INFLUENCE DEMONSTRATED INABILITY TO COMPLY		No/ 2020-08-31 (1)	Physician Decision/ RANDOMIZED IN ERROR -DID NOT RECEIVE ANY DOSES OF IP--NOT APPROPRIATE FOR PARTICIPATION PER INVESTIGATOR DURING EXAM--WAS INCOHERENT AND APPEARED TO BE UNDER INFLUENCE DEMONSTRATED INABILITY TO COMPLY

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3212254	2020-08-19	2	No/ 2020-09-05 (18)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT ON 05SEP2020 DUE TO UNFORESEEN PERSONAL CIRCUMSTANCES, EVERY ATTEMPT WAS MADE BY SITE STAFF TO KEEP THE SUBJECT IN THE STUDY HOWEVER SHE DOES NOT WISH TO CONTINUE FURTHER.		No/ 2020-09-05 (18)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT ON 05SEP2020 DUE TO UNFORESEEN PERSONAL CIRCUMSTANCES, EVERY ATTEMPT WAS MADE BY SITE STAFF TO KEEP THE SUBJECT IN THE STUDY HOWEVER SHE DOES NOT WISH TO CONTINUE FURTHER.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3252144	2020-08-12	2	No/ 2020-08-12 (1)	Other/ SUBJECT IS HIV POSITIVE AND SPONSOR DECIDED TO HOLD OFF SCREENING/DOSING HIV POSITIVE PATIENTS DESPITE AMD 3 APPROVAL.		No/ 2020-08-12 (1)	Other/ SUBJECT IS HIV POSITIVE AND SPONSOR DECIDED TO HOLD OFF SCREENING/DOSING HIV POSITIVE PATIENTS DESPITE AMD 3 APPROVAL.
US3332089	2020-09-17	3	ONGOING			No/ 2020-09-18 (2)	Due to SARS-CoV-2
US3402300	2020-08-08	2	ONGOING			No/ 2020-09-09 (33)	Adverse Event/ AE #1

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3602037	2020-09-14	3	No/ 2020-09-25 (12)	Adverse Event/ AE LOG LINE 1 AEID: USA-US079-2020-MRNA-1273-P3010000 02		No/ 2020-09-25 (12)	Adverse Event/ A.E LOG LINE #1
US3772024	2020-08-06	1	No/ 2020-08-06 (1)	Withdrawal of Consent by Participant/ SUBJECT W/C PRIOR TO IP ADMINISTRATION.		No/ 2020-08-06 (1)	Withdrawal of Consent by Participant/ SUBJECT W/C PRIOR TO DOSE ADMINISTRATION.
US3772237	2020-09-10	3	No/ 2020-09-10 (1)	Other/ SUBJECT WITHDRAWN DUE TO INABILITY TO DRAW BLOOD		No/ 2020-09-10 (1)	Other/ SUBJECT WITHDRAWN DUE TO INABILITY TO DRAW BLOOD

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3872177	2020-08-13	2	No/ 2020-08-13 (1)	Withdrawal of Consent by Participant/ SUBJECT DID NOT HAVE THE TIME TO WAIT TO BE SEEN AT THE VISIT AS THE CLINIC WAS BUSY. SUBJECT WITHDREW CONSENT AND DID NOT WISH TO PARTICIPATE.		No/ 2020-08-13 (1)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT PRIOR TO RECEIVING DOSE
US3902076	2020-09-11	3	No/ 2020-11-11 (62)	Other/ SUBJECT COULD NOT GET BLOOD DRAWN		No/ 2020-11-11 (62)	Other/ SUBJECT COULD NOT GET BLOOD DRAWN

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3902113	2020-09-25	3	No/ 2020-09-25 (1)	Other/ UNABLE TO COMPLETE BLOOD DRAW		No/ 2020-09-25 (1)	Other/ UNABLE TO COMPLETE BLOOD DRAW
US3902114	2020-09-25	3	No/ 2020-09-25 (1)	Other/ NO LONGER WANTED TO PARTICIPATE		No/ 2020-09-25 (1)	Other/ NO LONGER WANTED TO PARTICIPATE
US3902131	2020-10-16	3	No/ 2020-10-16 (1)	Other/ UNABLE TO DRAW BLOOD		No/ 2020-10-16 (1)	Other/ UNABLE TO DRAW BLOOD

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3982070	2020-09-01	3	No/ 2020-10-27 (57)	Withdrawal of Consent by Participant/ SUBJECT WAS RANDOMIZED 01 SEP 2020 BUT IP WAS NOT DISPENSED.		No/ 2020-10-27 (57)	Withdrawal of Consent by Participant/ SUBJECT WAS RANDOMIZED 01 SEP 2020 BUT IP WAS NOT DISPENSED.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3002031	2020-07-28	1	ONGOING			No/ 2020-09-28 (63)	Due to SARS-CoV-2
US3002046	2020-07-29	1	No/ 2020-11-06 (101)	Withdrawal of Consent by Participant/ PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P301000001		No/ 2020-11-06 (101)	Serious Adverse Event/ PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P301000001

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3002231	2020-09-02	3	ONGOING			No/ 2020-10-06 (35)	Physician Decision/ PATIENT CAME IN FOR 2ND VACCINATION BUT HAD COVID LIKE ILLNESS AND COMPLETED ILLNESS VISIT INSTEAD. PATIENT POSITIVE FOR RHINOVIRUS AND STILL HAVING SYMPTOMS ON LAST DAY OF VISIT 2 WINDOW.
US3002302	2020-09-15	3	ONGOING			No/ 2020-10-13 (29)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3012041	2020-07-31	1	ONGOING			No/ 2020-08-28 (29)	Physician Decision/ SUBJECT HAD ELECTIVE SURGERY. PER PI DECISION, DOSE #2 WAS SKIPPED.
US3012137	2020-08-14	2	No/ 2020-11-16 (95)	Lost to Follow-Up		Yes/ 2020-09-11 (29)	
US3012181	2020-08-19	2	ONGOING			No/ 2020-09-17 (30)	Protocol Deviation/ RECEIVED A NON TRIAL VACCINE

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3012188	2020-08-19	2	No/ 2020-09-18 (31)	Withdrawal of Consent by Participant/ PT DOES NOT WANT TO EXPERIENCE SIDE EFFECTS AGAIN AND IS DISCONTINUING PARTICIPATION FROM STUDY PRIOR TO SECOND VACCINE.		No/ 2020-09-18 (31)	Withdrawal of Consent by Participant/ PT DOES NOT WANT TO EXPERIENCE SIDE EFFECTS AGAIN AND IS DISCONTINUING PARTICIPATION FROM STUDY PRIOR TO SECOND VACCINE.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3012194	2020-08-20	2	ONGOING			No/ 2020-09-17 (29)	Protocol Deviation/ SUBJECT RECEIVED INFLUENZA VACCINE IN BETWEEN DOSES AND SECOND DOSE COULD NOT BE ACCOMMODATED IN WINDOW.
US3032027	2020-07-28	1	No/ 2020-10-11 (76)	Lost to Follow-Up		Yes/ 2020-08-28 (32)	
US3032034	2020-07-29	1	No/ 2020-08-26 (29)	Withdrawal of Consent by Participant/ UNABLE TO COMPLY WITH STUDY PROCEDURES		No/ 2020-08-26 (29)	Withdrawal of Consent by Participant/ UNABLE TO COMPLY WITH STUDY PROCEDURES

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3032171	2020-08-10	2	ONGOING			No/ 2020-09-21 (43)	Due to SARS-CoV-2
US3032172	2020-08-10	2	ONGOING			No/ 2020-09-08 (30)	Due to SARS-CoV-2
US3032204	2020-08-14	2	No/ 2020-11-16 (95)	Death	2020-11-16/ UNK	Yes/ 2020-09-14 (32)	
US3032240	2020-08-19	2	No/ 2020-10-20 (63)	Lost to Follow-Up		No/ 2020-10-20 (63)	Lost to Follow-Up
US3032277	2020-08-20	2	No/ 2020-10-01 (43)	Serious Adverse Event/ SAE #1		No/ 2020-10-01 (43)	Serious Adverse Event/ SAE LINE 1
US3042051	2020-08-03	1	ONGOING			No/ 2020-08-31 (29)	Due to SARS-CoV-2

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3042158	2020-08-12	2	No/ 2020-11-05 (86)	Withdrawal of Consent by Participant/ SUBJECT BELIEVES A VACCINE WILL BE AVAILABLE TO THE PUBLIC NEXT MONTH; SUBJECT WITHDREW CONSENT.		Yes/ 2020-09-09 (29)	
US3042171	2020-08-13	2	No/ 2020-09-05 (24)	Lost to Follow-Up		No/ 2020-09-05 (24)	Lost to Follow-Up
US3042209	2020-08-14	2	ONGOING			No/ 2020-09-08 (26)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3042295	2020-08-21	2	No/ 2020-09-21 (32)	Withdrawal of Consent by Participant/ SUBJECT WAS DIAGNOSED WITH VERTIGO AND WISHED TO NOT PARTICIPANT IS STUDY ANY FURTHER TO FOCUS ON THEIR HEALTH		No/ 2020-09-21 (32)	Withdrawal of Consent by Participant/ SUBJECT WAS DIAGNOSED WITH VERTIGO AND WISHED TO NOT PARTICIPANT IS STUDY ANY FURTHER TO FOCUS ON THEIR HEALTH

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3052069	2020-08-03	1	No/ 2020-09-03 (32)	Withdrawal of Consent by Participant/ PATIENT WAS CONTACTED TO RESCHEDULE APPOINTMENT AND WITHDREW		No/ 2020-09-03 (32)	Withdrawal of Consent by Participant/ THE PATIENT LEFT HER APPOINTMENT AND WHEN CONTACTED TO RESCHEDULE SHE WITHDREW HER CONSENT.
US3082247	2020-09-16	3	ONGOING			No/ 2020-10-26 (41)	Due to SARS-CoV-2
US3082269	2020-09-21	3	No/ 2020-10-03 (13)	Death	2020-10-03/ UNK	No/ 2020-10-03 (13)	Death

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3092003	2020-08-04	1	No/ 2020-10-09 (67)	Physician Decision/ PHYSICIAN DECISION PER NON COMPLIANCE AFTER SEVERAL FAILED CALL ATTEMPTS TO SUBJECT.		No/ 2020-10-09 (67)	Physician Decision/ SUBJECT WITHDREW DUE TO ONLINE SCHOOLING. LATER CALLED SITE TO SCHEDULE NEXT VISIT. AFTER EPIP WAS SUBMITTED SUBJECT NEVER RESPONDED TO SITE CALLS.

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3092018	2020-08-05	1	ONGOING			No/ 2020-08-31 (27)	Withdrawal of Consent by Participant/ SUBJECT RETURNED TO SITE TO RETURN E-DIARY DEVICE AND WITHDREW CONSENT. SITE ATTEMPTED TO CONTACT SUBJECT AS NO REASON AS TO WHY SUBJECT WAS WITHDRAWING FROM STUDY WAS GIVEN.
US3092059	2020-08-07	1	No/ 2020-10-23 (78)	Withdrawal of Consent by Participant/ DUE TO WORK SCHEDULE		No/ 2020-10-23 (78)	Withdrawal of Consent by Participant/ DUE TO WORK SCHEDULE

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3092109	2020-08-11	2	ONGOING			No/ 2020-10-29 (80)	Withdrawal of Consent by Participant/ DONE
US3102071	2020-07-30	1	No/ 2020-08-31 (33)	Withdrawal of Consent by Participant/ PARTICIPANT DOES NOT WANT TO DO ANOTHER NP SWAB AT VISIT 2.		No/ 2020-08-31 (33)	Withdrawal of Consent by Participant/ PARTICIPANT DOES NOT WANT TO DO ANOTHER NP SWAB AT VISIT 2.

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3102404	2020-09-30	3	No/ 2020-10-27 (28)	Withdrawal of Consent by Participant/ SUBJECT STATED HE WISHED TO WITHDRAW CONSENT DUE TO LENGTH IT TOOK TO TRAVEL TO THE SITE		No/ 2020-10-27 (28)	Withdrawal of Consent by Participant/ SUBJECT STATED HE WISHED TO WITHDRAW CONSENT DUE TO LENGTH IT TOOK TO TRAVEL TO THE SITE

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3112252	2020-08-14	2	No/ 2020-09-30 (48)	Withdrawal of Consent by Participant/ PT HAS AGREED TO WITHDRAW CONSENT DUE TO UPCOMING TOTAL KNEE REPLACEMENT CITING POTENTIAL INABILITY TO COMPLY FULLY WITH STUDY PROCEDURES. PT HAS ALSO DEMONSTRATED TENDENCY OF NON-COMPLIANCE.		No/ 2020-09-30 (48)	Withdrawal of Consent by Participant/ PT RESPONDED TO MISSED APPTS THROUGH CALL, AGREED TO WITHDRAW CONSENT DUE TO UPCOMING TOTAL KNEE REPLACEMENT SURGERY CITING POTENTIAL INABILITY TO COMPLY FULLY WITH STUDY PROCEDURES.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3112266	2020-08-14	2	ONGOING			No/ 2020-09-13 (31)	Due to SARS-CoV-2
US3112267	2020-08-14	2	ONGOING			No/ 2020-09-13 (31)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3122127	2020-07-29	1	No/ 2020-09-14 (48)	Withdrawal of Consent by Participant/ PATIENT LEFT SITE AT DAY 29 PRIOR TO IP ADMINISTRATION. CALLED SITE ON 14-SEP-2020 TO SAY THEY NO LONGER WISHED TO PARTICIPATE IN THE STUDY AND WITHDREW CONSENT.		No/ 2020-09-14 (48)	Withdrawal of Consent by Participant/ PATIENT LEFT SITE AT DAY 29 PRIOR TO IP ADMINISTRATION. CALLED SITE ON 14-SEP-2020 TO SAY THEY NO LONGER WISHED TO PARTICIPATE IN THE STUDY AND WITHDREW CONSENT.
US3152025	2020-07-29	1	ONGOING			No/ 2020-08-24 (27)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3152124	2020-08-10	2	No/ 2020-09-29 (51)	Lost to Follow-Up		Yes/ 2020-09-08 (30)	
US3152217	2020-08-14	2	No/ 2020-09-29 (47)	Other/ SUBJECT MOVING TO (b)(6) UNEXPECTEDLY		Yes/ 2020-09-11 (29)	
US3152283	2020-08-17	2	No/ 2020-11-05 (81)	Withdrawal of Consent by Participant/ WITHDREW CONSENT DUE TO BELIEVING HE HAD RECEIVED PLACEBO.		Yes/ 2020-09-16 (31)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3152319	2020-08-20	2	No/ 2020-09-22 (34)	Withdrawal of Consent by Participant/ WITHDREW CONSENT DUE TO REFUSAL TO DO NASAL COVID TESTING		No/ 2020-09-22 (34)	Withdrawal of Consent by Participant/ WITHDREW DUE TO REFUSAL TO DO NASAL COVID TESTING
US3152410	2020-09-28	3	No/ 2020-10-05 (8)	Withdrawal of Consent by Participant/ SUBJECT BELIEVED HE RECEIVED PLACEBO AND DID NOT WANT TO CONTINUE		No/ 2020-10-05 (8)	Withdrawal of Consent by Participant/ SUBJECT THINKS HE RECEIVED PLACEBO

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3152544	2020-10-22	4	No/ 2020-10-29 (8)	Withdrawal of Consent by Participant/ PARTICIPANT IS MOVING OUT OF THE AREA AND UNABLE TO COMPLETE FOLLOW UP CALLS OR VISITS.		No/ 2020-10-29 (8)	Withdrawal of Consent by Participant/ PARTICIPANT IS MOVING OUT OF THE AREA AND UNABLE TO COMPLETE FOLLOW UP CALLS OR VISITS.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3162243	2020-09-16	3	No/ 2020-10-14 (29)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER WISHES TO PARTICIPATE IN THE STUDY. THEY STATED THEY DID NOT HAVE TIME TO DEVOTE TO STUDY PARTICIPATION AND MAKING IT TO THE VISITS. AND THAT THEY LIVED A DISTANCE AWAY.		No/ 2020-10-14 (29)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER WISHES TO PARTICIPATE IN THE STUDY. THEY STATED THEY DID NOT HAVE TIME TO DEVOTE TO STUDY PARTICIPATION AND MAKING IT TO THE VISITS. AND THAT THEY LIVED A DISTANCE AWAY.
US3172002	2020-08-07	1	No/ 2020-09-24 (49)	Lost to Follow-Up		No/ 2020-09-24 (49)	Lost to Follow-Up

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172009	2020-08-07	1	ONGOING			No/ 2020-09-12 (37)	Other/ MISSED VISIT.
US3172015	2020-08-10	1	No/ 2020-09-15 (37)	Withdrawal of Consent by Participant/ SUBJECT NOT BEING COMPLIANT WITH INCLUSION #3		Yes/ 2020-09-04 (26)	
US3172022	2020-08-10	1	ONGOING			No/ 2020-09-15 (37)	Other/ MISSED VISIT

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172027	2020-08-11	1	No/ 2020-09-08 (29)	Withdrawal of Consent by Participant/ NO LONGER INTERESTED IN STUDY PARTICIPATION.		No/ 2020-09-08 (29)	Withdrawal of Consent by Participant/ NO LONGER INTERESTED IN STUDY PARTICIPATION.
US3172052	2020-08-11	1	No/ 2020-09-08 (29)	Withdrawal of Consent by Participant/ SUBJECT MOVING TO (b) (6)		No/ 2020-09-08 (29)	Withdrawal of Consent by Participant/ SUBJECT MOVING TO (b) (6)
US3172053	2020-08-11	1	No/ 2020-09-08 (29)	Withdrawal of Consent by Participant/ SUBJECT MOVING TO (b) (6)		No/ 2020-09-08 (29)	Withdrawal of Consent by Participant/ SUBJECT MOVING TO (b) (6)

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172069	2020-08-12	1	ONGOING			No/ 2020-09-09 (29)	Serious Adverse Event/ SAE #1
US3172150	2020-08-17	1	ONGOING			No/ 2020-09-22 (37)	Other/ MISSED VISIT.
US3172165	2020-08-18	1	No/ 2020-09-15 (29)	Withdrawal of Consent by Participant/ SUBJECT DECIDED TO WITHDRAW CONSENT		No/ 2020-09-15 (29)	Withdrawal of Consent by Participant/ SUBJECT DECIDED TO WITHDRAW CONSENT

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172177	2020-08-18	1	ONGOING			No/ 2020-09-29 (43)	Withdrawal of Consent by Participant/ SUBJECT CANNOT CONTINUE IN TRIAL. SUBJECT DECIDED TO WITHDRAW CONSENT DUE TO BUSY SCHEDULE AT WORK IN (b) (6)
US3172178	2020-08-18	1	ONGOING			No/ 2020-09-23 (37)	Other/ MISSED VISIT.
US3172215	2020-08-19	2	ONGOING			No/ 2020-09-24 (37)	Other/ MISSED VISIT DAY 29
US3172218	2020-08-19	1	ONGOING			No/ 2020-09-24 (37)	Other/ MISSED VISIT

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172241	2020-08-20	1	ONGOING			No/ 2020-09-25 (37)	Other/ SKIPPED VISIT
US3172247	2020-08-20	1	ONGOING			No/ 2020-09-25 (37)	Other/ MISSED VISIT.
US3172255	2020-08-20	1	ONGOING			No/ 2020-09-25 (37)	Other/ MISSED VISIT
US3172260	2020-08-21	1	ONGOING			No/ 2020-09-26 (37)	Other/ MISSED VISIT
US3172273	2020-08-21	2	No/ 2020-09-30 (41)	Withdrawal of Consent by Participant/ MOVED TO (b) (6) (b) (6)		No/ 2020-09-30 (41)	Withdrawal of Consent by Participant/ MOVED TO (b) (6) (b) (6)

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172294	2020-08-24	2	ONGOING			No/ 2020-09-28 (36)	Other/ MISSED VISIT
US3172308	2020-08-25	3	No/ 2020-09-30 (37)	Lost to Follow-Up		Yes/ 2020-09-21 (28)	
US3172320	2020-08-25	3	ONGOING			No/ 2020-09-21 (28)	Other/ SUBJECT DECLINED SECOND DOSE DUE TO SOLICITED ADVERSE REACTION SYMPTOMS PRESENTED AT DAY 1 DOSE VACCINATION

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172335	2020-08-25	2	No/ 2020-10-02 (39)	Withdrawal of Consent by Participant/ SUBJECT DECIDED TO WITHDRAW CONSENT		No/ 2020-10-02 (39)	Withdrawal of Consent by Participant/ SUBJECT DECIDED TO WITHDRAW CONSENT
US3172349	2020-08-26	3	ONGOING			No/ 2020-09-23 (29)	Pregnancy
US3172372	2020-08-27	3	ONGOING			No/ 2020-10-02 (37)	Other/ SUBJECT DID NOT COME TO THE VISIT.
US3172384	2020-10-16	2	No/ 2020-10-20 (5)	Other/ EXCLUSION # 10		No/ 2020-10-20 (5)	Other/ EXCLUSION # 10
US3172403	2020-10-19	2	No/ 2020-11-16 (28)	Other/ INCLUSION #3		No/ 2020-11-16 (28)	Other/ INCLUSION #3

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3182292	2020-08-11	2	ONGOING			No/ 2020-09-01 (22)	Due to SARS-CoV-2
US3192078	2020-08-06	1	No/ 2020-09-16 (42)	Withdrawal of Consent by Participant/ PATIENT DECIDED TO DISCONTINUE TRIAL		No/ 2020-09-16 (42)	Withdrawal of Consent by Participant/ PATIENT DECIDED TO WITHDRAWAL PARTICIPATION, STATED SHE DOESNT THINK THIS TRIAL IS FOR HER.
US3192090	2020-08-06	1	No/ 2020-08-31 (26)	Withdrawal of Consent by Participant/ PATIENT DECIDED SITE AND TRIAL NOT FOR HER		No/ 2020-08-31 (26)	Withdrawal of Consent by Participant/ PATIENT DECIDED SITE AND TRIAL NOT FOR HER

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3192109	2020-08-07	1	No/ 2020-09-03 (28)	Withdrawal of Consent by Participant/ SUBJECT DECIDED TO WITHDRAWAL ICF, STATED HE FELT HE RECEIVED PLACEBO AND THERE'S NO NEED FOR HIM TO CONTINUE.		No/ 2020-09-03 (28)	Withdrawal of Consent by Participant/ SUBJECT DECIDED TO WITHDRAWAL ICF, STATED HE FELT HE RECEIVED PLACEBO AND THERE'S NO NEED FOR HIM TO CONTINUE.
US3192314	2020-08-17	1	No/ 2020-10-19 (55)	Lost to Follow-Up		No/ 2020-10-19 (55)	Lost to Follow-Up

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3192461	2020-08-24	2	No/ 2020-10-22 (60)	Withdrawal of Consent by Participant/ PATIENT DID NOT WANT TO PARTICIPATE ANY LONG IN THE TRIAL		No/ 2020-10-22 (60)	Withdrawal of Consent by Participant/ PATIENT STATED THAT HE DID NOT WANT TO PARTICIPATE WITH THE TRIAL ANY LONGER
US3192554	2020-08-28	3	No/ 2020-10-06 (40)	Withdrawal of Consent by Participant/ PATIENT STATED SHE HAS MOVED AWAY AND NO LONGER WILL BE ABLE TO ME APPTS.		No/ 2020-10-06 (40)	Withdrawal of Consent by Participant/ PT HAS MOVED AWAY

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3192603	2020-08-31	3	ONGOING			No/ 2020-09-30 (31)	Withdrawal of Consent by Participant/ PATIENTS PRIMARY CARE RECOMMENDED THAT PATIENT DOES NOT CONTINUE IN THE STUDY DUE TO ELEVATED BLOOD PRESSURE READINGS.
US3192733	2020-10-04	4	ONGOING			No/ 2020-11-03 (31)	Other/ PATIENT DECLINED 2ND INJECTION

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202148	2020-08-12	2	No/ 2020-10-01 (51)	Withdrawal of Consent by Participant/ SUBJECT CONVINCED HE GOT PLACEBO SO HE REFUSED TO COME BACK		No/ 2020-10-01 (51)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT FROM STUDY AND REFUSED TO CONTINUE W/ FOLLOWUP.
US3202164	2020-08-13	2	ONGOING			No/ 2020-11-17 (97)	Other/ SUBJECT'S INCREASED WORKLOAD AND SCHEDULE PREVENTED HER FROM KEEPING APPOINTMENTS- DECLINED ANY FUTURE SITE VISITS

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202245	2020-08-18	2	No/ 2020-10-01 (45)	Lost to Follow-Up		No/ 2020-10-01 (45)	Lost to Follow-Up
US3202364	2020-08-31	3	No/ 2020-09-30 (31)	Withdrawal of Consent by Participant/ SUBJECT REPORTS THAT HE KNOWS HE GOT PLACEBO SO HE DOESN'T WANT TO TO CONTINUE IN STUDY. HE GOT AN ANTIBODY TEST LAST WEEK THAT WAS NEGATIVE AND DID NOT WISH TO DISCUSS CONTINUING		No/ 2020-09-30 (31)	Withdrawal of Consent by Participant/ SUBJECT REPORTS THAT HE KNOWS HE GOT PLACEBO SO HE DOESN'T WANT TO TO CONTINUE IN STUDY. HE GOT AN ANTIBODY TEST LAST WEEK THAT WAS NEGATIVE AND DID NOT WISH TO DISCUSS CONTINUING

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3212112	2020-08-10	2	ONGOING			No/ 2020-10-26 (78)	Other/ PARTICIPANT MISSED VACCINE 2 WINDOW DUE TO TRANSFER TO US363. VACCINE WINDOW CLOSED ON SEPT 14. PARTICIPANT STARTED WITH COVID SYMPTOMS ON 14OCT2020 AND TESTED POSITIVE OUTSIDE OF STUDY ON 16OCT2020.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3212198	2020-08-17	2	No/ 2020-09-12 (26)	Withdrawal of Consent by Participant/ SUBJECT CALLED TO WITHDRAW CONSENT ON 12SEP2020 DUE TO PERSONAL CIRCUMSTANCES, ALL ATTEMPTS WERE MADE BY SITE STAFF TO KEEP SUBJECT IN THE STUDY, HOWEVER SHE WISHED TO DISCONTINUE FROM THE STUDY.		No/ 2020-09-12 (26)	Withdrawal of Consent by Participant/ SUBJECT CALLED TO WITHDRAW CONSENT ON 12SEP2020 DUE TO PERSONAL CIRCUMSTANCES, ALL ATTEMPTS WERE MADE BY SITE STAFF TO KEEP SUBJECT IN THE STUDY, HOWEVER SHE WISHED TO DISCONTINUE FROM THE STUDY.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3212225	2020-08-18	2	No/ 2020-09-15 (29)	Withdrawal of Consent by Participant/ SUBJECT DENIED COMING IN FOR AN ILLNESS VISIT ON 11SEP2020 AND WITHDREW CONSENT ON 15SEP2020. ALL ATTEMPTS WERE MADE TO KEEP THE SUBJECT IN THE STUDY, HOWEVER HE DID NOT WISH TO CONTINUE.		No/ 2020-09-15 (29)	Withdrawal of Consent by Participant/ SUBJECT DENIED COMING IN FOR AN ILLNESS VISIT ON 11SEP2020 AND WITHDREW CONSENT ON 15SEP2020. ALL ATTEMPTS WERE MADE TO KEEP THE SUBJECT IN THE STUDY, HOWEVER HE DID NOT WISH TO CONTINUE.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222015	2020-08-06	1	No/ 2020-09-12 (38)	Withdrawal of Consent by Participant/ PT W/D CONSENT		No/ 2020-09-12 (38)	Withdrawal of Consent by Participant/ PT W/D CONSENT
US3222031	2020-08-07	1	No/ 2020-09-06 (31)	Withdrawal of Consent by Participant/ PT DOES NOT WANT FURTHER AES.		No/ 2020-09-06 (31)	Withdrawal of Consent by Participant/ DOES NOT WANT FURTHER AES

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222088	2020-08-11	1	No/ 2020-09-04 (25)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT BECAUSE SHE DID NOT WANT TO CONTINUE WITHOUT HER HUSBAND WHOM ALSO WITHDREW CONSENT.		No/ 2020-09-04 (25)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT BECAUSE SHE DID NOT WANT TO CONTINUE WITHOUT HER HUSBAND WHOM ALSO WITHDREW CONSENT.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222102	2020-08-12	1	No/ 2020-08-25 (14)	Withdrawal of Consent by Participant/ THE SUBJECT IS WITHDRAWING CONSENT FROM TRIAL AND MOVING OUT OF STATE.		No/ 2020-08-25 (14)	Withdrawal of Consent by Participant/ THE SUBJECT IS WITHDRAWING CONSENT FROM TRIAL AND MOVING OUT OF STATE.
US3222104	2020-08-12	1	No/ 2020-09-16 (36)	Withdrawal of Consent by Participant/ PT W/C DUE TO DISTANCE		Yes/ 2020-09-09 (29)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222229	2020-08-19	2	No/ 2020-09-24 (37)	Withdrawal of Consent by Participant/ PT WITHDREW CONSENT		Yes/ 2020-09-17 (30)	
US3222249	2020-08-20	2	No/ 2020-09-26 (38)	Lost to Follow-Up		No/ 2020-09-26 (38)	Lost to Follow-Up
US3222271	2020-08-22	2	No/ 2020-09-12 (22)	Withdrawal of Consent by Participant/ CANNOT COMPLY WITH VISIT SCHEDULE		No/ 2020-09-12 (22)	Withdrawal of Consent by Participant/ CANNOT COMPLY WITH VISIT SCHEDULE.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222288	2020-08-23	2	No/ 2020-10-19 (58)	Withdrawal of Consent by Participant/ CONFLICT WITH VISIT SCHEDULED		No/ 2020-10-19 (58)	Withdrawal of Consent by Participant/ CONFLICT WITH VISIT SCHEDULE
US3222424	2020-08-31	3	ONGOING			No/ 2020-09-21 (22)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222434	2020-09-01	3	No/ 2020-11-07 (68)	Withdrawal of Consent by Participant/ AFTER MULTIPLE ATTEMPTS TO CONTACT SUBJECT RECEPTIONIST GOT A CALL AND SHE JUST ISN'T INTERESTED ANY LONGER.		Yes/ 2020-10-01 (31)	
US3222435	2020-09-01	3	No/ 2020-10-01 (31)	Withdrawal of Consent by Participant/ SUBJECT STATED NO LONGER INTERESTED		No/ 2020-10-01 (31)	Withdrawal of Consent by Participant/ SUBJECT STATED NO LONGER INTERESTED

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222464	2020-09-03	3	No/ 2020-10-26 (54)	Withdrawal of Consent by Participant/ WORK CONFLICT		No/ 2020-10-26 (54)	Withdrawal of Consent by Participant/ DUE TO SCHEDULING CONFLICT WITH WORK UNABLE TO CONTINUE THE TRIAL.
US3222466	2020-09-03	3	No/ 2020-10-26 (54)	Withdrawal of Consent by Participant/ SCHEDULING CONFLICT		No/ 2020-10-26 (54)	Withdrawal of Consent by Participant/ SCHEDULING CONFLICT
US3242002	2020-08-06	1	ONGOING			No/ 2020-08-26 (21)	Due to SARS-CoV-2
US3242258	2020-08-31	3	ONGOING			No/ 2020-11-05 (67)	Adverse Event/ AE #2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3252020	2020-08-04	1	ONGOING			No/ 2020-09-04 (32)	Due to SARS-CoV-2
US3252397	2020-08-31	3	No/ 2020-09-10 (11)	Lost to Follow-Up		No/ 2020-09-10 (11)	Lost to Follow-Up
US3272025	2020-07-31	1	No/ 2020-09-22 (54)	Lost to Follow-Up		No/ 2020-09-22 (54)	Lost to Follow-Up
US3272070	2020-08-06	1	No/ 2020-10-01 (57)	Death	2020-10-01/ UNK	Yes/ 2020-09-03 (29)	
US3272114	2020-08-12	2	No/ 2020-10-27 (77)	Lost to Follow-Up		No/ 2020-10-27 (77)	Lost to Follow-Up
US3272159	2020-08-15	2	No/ 2020-10-27 (74)	Lost to Follow-Up		No/ 2020-10-27 (74)	Lost to Follow-Up

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3272201	2020-08-20	2	No/ 2020-11-06 (79)	Withdrawal of Consent by Participant/ SUBJECT DOES NOT WISH TO CONTINUE IN STUDY AND DOESN'T SPECIFY WHY		Yes/ 2020-09-18 (30)	
US3282031	2020-08-11	2	No/ 2020-08-26 (16)	Withdrawal of Consent by Participant/ PT DOES NOT WISH TO CONTINUE, NO FURTHER DETAILS GIVEN.		No/ 2020-08-26 (16)	Withdrawal of Consent by Participant/ PT DOES NOT WISH TO CONTINUE, NO FURTHER DETAILS GIVEN.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3292144	2020-08-13	2	No/ 2020-09-17 (36)	Withdrawal of Consent by Participant/ PT NO LONGER WANTS TO PARTICIPATE DUE TO NOT HAVING ANY TIME TO COMPLETE STUDY PROCEDURES. VERBALLY WITHDREW CONSENT.		No/ 2020-09-17 (36)	Withdrawal of Consent by Participant/ PT NO LONGER WANTS TO PARTICIPATE DUE TO NOT HAVING ANY TIME TO COMPLETE STUDY PROCEDURES. VERBALLY WITHDREW CONSENT.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3292159	2020-08-13	2	No/ 2020-09-28 (47)	Withdrawal of Consent by Participant/ PT REPORTS FAMILY MEMBER FALLING ILL, UNABLE TO COMMIT TO STUDY PROCEDURES AND VISITS. VERBALLY WITHDREW CONSENT.		No/ 2020-09-28 (47)	Withdrawal of Consent by Participant/ PT REPORTS FAMILY MEMBER FALLING ILL, UNABLE TO COMMIT TO STUDY PROCEDURES AND VISITS. VERBALLY WITHDREW CONSENT.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3292192	2020-08-15	2	No/ 2020-09-25 (42)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DUE TO CONCERN OF RECEIVING PLACEBO		No/ 2020-09-25 (42)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DUE TO CONCERN OF RECEIVING PLACEBO, OPTIONS TO STAY IN THE STUDY WERE DISCUSSED WITH SUBJECT, BUT HE WAS ADAMANT WITH DECISION.
US3302163	2020-08-12	1	No/ 2020-11-04 (85)	Other/ SUBJECT DECISION		Yes/ 2020-09-09 (29)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3302179	2020-08-13	2	No/ 2020-09-21 (40)	Withdrawal of Consent by Participant/ SUBJECT STATES HE IS NO LONGER ABLE TO PARTICIPATE IN TRIAL.		No/ 2020-09-21 (40)	Withdrawal of Consent by Participant/ SUBJECT STATES HE IS NO LONGER ABLE TO PARTICIPATE IN TRIAL.
US3302383	2020-08-26	3	ONGOING			No/ 2020-09-29 (35)	Due to SARS-CoV-2
US3302446	2020-08-31	3	No/ 2020-09-28 (29)	Withdrawal of Consent by Participant/ SUBJECT MOVING STATES		No/ 2020-09-28 (29)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW DUE TO MOVING TO A DIFFERENT STATE.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3312068	2020-08-13	2	ONGOING			No/ 2020-08-28 (16)	Due to SARS-CoV-2
US3312097	2020-08-17	2	No/ 2020-09-08 (23)	Lost to Follow-Up		No/ 2020-09-08 (23)	Lost to Follow-Up
US3312201	2020-08-20	2	ONGOING			No/ 2020-09-17 (29)	Adverse Event/ AE#1
US3312212	2020-08-21	2	ONGOING			No/ 2020-09-18 (29)	Serious Adverse Event/ SAE#1
US3312470	2020-09-02	3	No/ 2020-09-23 (22)	Lost to Follow-Up		No/ 2020-09-23 (22)	Lost to Follow-Up
US3312548	2020-09-08	3	ONGOING			No/ 2020-10-12 (35)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3312587	2020-09-09	3	ONGOING			No/ 2020-10-12 (34)	Due to SARS-CoV-2
US3322006	2020-08-14	2	ONGOING			No/ 2020-09-09 (24)	Due to SARS-CoV-2
US3322061	2020-08-20	2	ONGOING			No/ 2020-09-16 (27)	Due to SARS-CoV-2

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3322082	2020-08-24	2	No/ 2020-11-09 (78)	Withdrawal of Consent by Participant/ ON 09 NOV 2020, SITE REACHED OUT TO SUBJECT TO RE-SCHEDULE HIS APPOINTMENT, EXPRESSED HE IS NO LONGER INTERESTED TO CONTINUE HIS PARTICIPATION IN THE STUDY.DISCONTINUED AS SUBJECT WITHDREW CONSENT.		Yes/ 2020-09-21 (29)	

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3322111	2020-08-26	2	No/ 2020-09-23 (29)	Withdrawal of Consent by Participant/ WITHDREW CONSENT DUE TO PERSONAL REASONS.		No/ 2020-09-23 (29)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DUE TO PERSONAL REASONS
US3322199	2020-09-02	3	No/ 2020-11-16 (76)	Death	2020-11-16/ UNK	Yes/ 2020-10-01 (30)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3322435	2020-10-15	4	No/ 2020-11-19 (36)	Withdrawal of Consent by Participant/ MISSED D29 VISIT, SITE REACHED OUT TO SUBJECT ONE MORE TIME TO RE-SCHEDULE HER APPOINTMENT AND SUBJECT EXPRESSED SHE IS NO LONGER INTERESTED TO CONTINUE HER PARTICIPATION IN THE STUDY.		No/ 2020-11-19 (36)	Withdrawal of Consent by Participant/ MISSED D29, SITE REACHED OUT TO SUBJECT ONE MORE TIME TO RE-SCHEDULE HER APPOINTMENT AND SUBJECT EXPRESSED SHE IS NO LONGER INTERESTED TO CONTINUE HER PARTICIPATION IN THE STUDY.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3332092	2020-09-23	3	No/ 2020-10-20 (28)	Withdrawal of Consent by Participant/ DOESN'T HAVE TIME		No/ 2020-10-20 (28)	Withdrawal of Consent by Participant/ DOESN'T HAVE TIME
US3332097	2020-10-12	4	No/ 2020-11-12 (32)	Withdrawal of Consent by Participant/ DOESN'T HAVE TIME FOR THE STUDY.		Yes/ 2020-11-06 (26)	
US3342066	2020-08-14	2	No/ 2020-10-05 (53)	Lost to Follow-Up		No/ 2020-10-05 (53)	Lost to Follow-Up
US3342088	2020-08-17	2	ONGOING			No/ 2020-09-17 (32)	Serious Adverse Event/ AE #1

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3342209	2020-09-08	3	No/ 2020-10-16 (39)	Withdrawal of Consent by Participant/ SUBJECT CHOSE TO WITHDRAW FROM STUDY		No/ 2020-10-16 (39)	Withdrawal of Consent by Participant/ SUBJECT CHOSE TO EXIT STUDY
US3342253	2020-09-11	3	ONGOING			No/ 2020-10-13 (33)	Adverse Event/ AE #1
US3342256	2020-09-14	3	No/ 2020-09-20 (7)	Death	2020-09-20/ UNK	No/ 2020-09-20 (7)	Death

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3342259	2020-09-14	3	No/ 2020-10-16 (33)	Adverse Event/ AE #2 DEPRESSION WITH SUICIDAL IDEATION, PI CHOSE TO WITHDRAW SUBJECT FROM STUDY		No/ 2020-10-16 (33)	Adverse Event/ AE #2, DEPRESSION WITH SUICIDAL IDEATION, PI CHOSE TO WITHDRAW SUBJECT
US3352013	2020-08-04	1	No/ 2020-09-02 (30)	Lost to Follow-Up		No/ 2020-09-02 (30)	Lost to Follow-Up
US3352035	2020-08-06	1	No/ 2020-10-28 (84)	Withdrawal of Consent by Participant/ WITHDREW CONSENT DUE TO PERSONAL REASONS, DID NOT DISCLOSE DETAILS.		Yes/ 2020-09-01 (27)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3352072	2020-08-13	2	ONGOING			No/ 2020-08-21 (9)	Due to SARS-CoV-2
US3362083	2020-08-08	1	ONGOING			No/ 2020-08-31 (24)	Due to SARS-CoV-2
US3362156	2020-08-15	2	No/ 2020-10-15 (62)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT, DID NOT DISCLOSE REASONING		Yes/ 2020-09-16 (33)	
US3362186	2020-08-18	2	No/ 2020-09-16 (30)	Withdrawal of Consent by Participant/ UNABLE TO MAKE STUDY VISITS		No/ 2020-09-16 (30)	Withdrawal of Consent by Participant/ UNABLE TO MAKE STUDY VISITS

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3362206	2020-08-20	2	No/ 2020-09-15 (27)	Withdrawal of Consent by Participant/ WITHDRAWAL OF CONSENT-NO EXPLANATION PROVIDED		No/ 2020-09-15 (27)	Withdrawal of Consent by Participant/ WITHDREW CONSENT-NO EXPLANATION PROVIDED
US3372028	2020-08-04	1	No/ 2020-08-27 (24)	Withdrawal of Consent by Participant/ DUE TO WORK SCHEDULE PATIENT CAN NO LONGER PARTICIPATE IN STUDY		No/ 2020-08-27 (24)	Withdrawal of Consent by Participant/ DUE TO WORK SCHEDULE PATIENT HAD TO WITHDRAW FROM STUDY

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3372107	2020-08-12	2	ONGOING			No/ 2020-09-23 (43)	Other/ SUBJECT DID NOT WANT TO RECEIVE SECOND SHOT
US3402192	2020-08-02	1	No/ 2020-09-04 (34)	Withdrawal of Consent by Participant/ SUBJECT WAS IN OFFICE FOR VISIT 2 BUT REFUSED TO WAIT FOR VACCINE PREPARATION. AT THAT TIME SUBJECT WITHDREW CONSENT AND LEFT FACILITY.			

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3402214	2020-08-04	1	No/ 2020-10-11 (69)	Lost to Follow-Up		Yes/ 2020-09-08 (36)	
US3402246	2020-08-05	1	No/ 2020-09-02 (29)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER WISHED TO PARTICIPATE		No/ 2020-09-02 (29)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER WISHED TO PARTICIPATE
US3402295	2020-08-08	2	No/ 2020-11-06 (91)	Withdrawal of Consent by Participant/ SUBJECT NOLONGER WANTED TO TRAVEL TO SITE		Yes/ 2020-09-11 (35)	
US3402430	2020-08-22	2	ONGOING			No/ 2020-09-21 (31)	Adverse Event/ AE 1

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3402441	2020-09-01	3	No/ 2020-11-07 (68)	Lost to Follow-Up		Yes/ 2020-09-28 (28)	
US3412146	2020-08-05	1	No/ 2020-10-28 (85)	Withdrawal of Consent by Participant/ SUBJECT IS WITHDRAWING CONSENT DUE TO NOT WANTING TO BE A PART OF THE STUDY ANYMORE DUE TO EXCESSIVE BLOOD DRAWS.		Yes/ 2020-09-03 (30)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3412278	2020-08-19	2	ONGOING			No/ 2020-09-16 (29)	Other/ DURING MONITOR VISIT OUR CRA IDENTIFIED SUBJECT AS (b) (6) (b) (6)
US3412314	2020-08-25	3	ONGOING			No/ 2020-09-21 (28)	Other/ SUBJECT WAS REQUESTED BY SPONSOR TO BE WITHDRAWN DUE TO (b) (6)

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3412328	2020-08-26	3	ONGOING			No/ 2020-10-06 (42)	Other/ SUBJECT HAD CHEST PAIN BETWEEN VISIT 1 AND VISIT 2. SUBJECT WAS MEDICALLY CLEARED OF SYMPTOMS BY VISIT 2, BUT HAS DECIDED THAT THEY DID NOT WANT THE SECOND DOSAGE. SUBJECT WILL CONTINUE IN STUDY.

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3412372	2020-09-15	3	No/ 2020-10-27 (43)	Withdrawal of Consent by Participant/ SUBJECT MOVED OUT OF STATE AND NO LONGER WANTED TO PARTAKE IN THE STUDY.		No/ 2020-10-27 (43)	Withdrawal of Consent by Participant/ SUBJECT MOVED OUT OF STATE AND WOULD BE UNABLE TO ATTEND ANY VISITS.
US3432023	2020-08-05	1	ONGOING			No/ 2020-08-26 (22)	Serious Adverse Event/ SAE #1
US3432295	2020-08-26	3	No/ 2020-10-02 (38)	Death	2020-10-02/ UNK	No/ 2020-10-02 (38)	Death

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3442167	2020-09-15	3	No/ 2020-11-13 (60)	Withdrawal of Consent by Participant/ SUBJECT IS UNABLE TO COMMIT TO STUDY REQUIREMENTS. SUBJECT WITHDREW CONSENT AFTER MULTIPLE ATTEMPTS TO ACCOMMODATE SUBJECT'S SCHEDULE.		Yes/ 2020-10-12 (28)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3442176	2020-09-16	3	No/ 2020-10-13 (28)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT AND DOES NOT WISH TO CONTINUE IN THE STUDY.		No/ 2020-10-13 (28)	Withdrawal of Consent by Participant/ PT DECIDED TO WITHDRAW CONSENT
US3452083	2020-08-01	1	No/ 2020-09-30 (61)	Withdrawal of Consent by Participant/ WITHDRAWAL OF CONSENT BY PARTICIPANT,		Yes/ 2020-08-29 (29)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3452084	2020-08-01	1	No/ 2020-10-06 (67)	Withdrawal of Consent by Participant/ PATIENT SAID SHE CAN NO LONGER MAKE STUDY VISITS		Yes/ 2020-09-08 (39)	
US3452165	2020-08-03	1	No/ 2020-10-05 (64)	Withdrawal of Consent by Participant/ PATIENT IS NO LONGER WILLING TO PARTICIPATE DUE TO PERSONAL REASONS		Yes/ 2020-09-01 (30)	

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3452255	2020-08-05	1	No/ 2020-08-26 (22)	Withdrawal of Consent by Participant/ SUBJECT DID NOT PROVIDE REASON FOR WITHDRAWING.			
US3452382	2020-09-22	3	No/ 2020-10-20 (29)	Withdrawal of Consent by Participant/ WITHDRAWAL OF CONSENT BY PARTICIPANT,		No/ 2020-10-20 (29)	Withdrawal of Consent by Participant/ WITHDRAWAL OF CONSENT BY PARTICIPANT,

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3462007	2020-08-03	1	No/ 2020-10-26 (85)	Withdrawal of Consent by Participant/ SUBJECT DOES NOT WANT TO BE CONTACTED BY SITE ANYMORE.		Yes/ 2020-09-04 (33)	
US3462132	2020-08-12	2	No/ 2020-09-14 (34)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT DUE TO FAMILY PROBLEMS		No/ 2020-09-14 (34)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT DUE TO FAMILY PROBLEMS.

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3462222	2020-08-18	2	No/ 2020-11-09 (84)	Withdrawal of Consent by Participant/ SUBJECT DOES NOT WISHED TO BE CONTACTED BY SITE ANYMORE.		Yes/ 2020-09-15 (29)	

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

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US3472019	2020-09-04	3	No/ 2020-10-09 (36)	Withdrawal of Consent by Participant/ PARTICIPANT'S FAMILY ASKED HIM TO DISCONTINUE HIS PARTICIPATION IN THE STUDY . PARTICIPANT WANTS TO BE RESPECTFUL OF THEIR WISHES.		No/ 2020-10-09 (36)	Withdrawal of Consent by Participant/ PARTICIPANT'S FAMILY ASKED HIM TO DISCONTINUE HIS PARTICIPATION IN THE STUDY . PARTICIPANT WANTS TO BE RESPECTFUL OF THEIR WISHES.
US3472082	2020-09-29	3	ONGOING			No/ 2020-10-27 (29)	Other/ PARTICIPANT REFUSED VACCINATION DUE TO SAFETY CONCERNS.

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3472096	2020-10-07	4	ONGOING			No/ 2020-11-09 (34)	Due to SARS-CoV-2
US3472130	2020-10-23	4	ONGOING			No/ 2020-11-03 (12)	Due to SARS-CoV-2
US3482145	2020-08-26	2	ONGOING			No/ 2020-09-23 (29)	Other/ DOES NOT MEET INCLUSION CRITERIA NUMBER 7
US3492117	2020-09-10	2	ONGOING			No/ 2020-09-26 (17)	Due to SARS-CoV-2
US3492242	2020-09-23	3	ONGOING			No/ 2020-10-05 (13)	Due to SARS-CoV-2

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Randomization Set

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Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3502103	2020-09-04	3	No/ 2020-10-30 (57)	Withdrawal of Consent by Participant/ PARTICIPANT CLAIMS SHE WAS NOT PAID IN A TIMELY MANNER		Yes/ 2020-10-02 (29)	
US3502167	2020-09-17	3	No/ 2020-11-11 (56)	Withdrawal of Consent by Participant/ AT THIS TIME, THE PARTICIPANT WISHES TO "OPT OUT."		Yes/ 2020-10-15 (29)	

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3512138	2020-08-22	2	No/ 2020-09-23 (33)	Withdrawal of Consent by Participant/ PT CALLED ON 9/23/2020 AND SPOKE COORDINATOR AND STATED HE CHANGED HIS MIND, THE PT ALSO STATED HIS WIFE READ SOME THINGS ABOUT THE TRIAL AND FOR PERSONAL REASON, HE WOULD RATHER NOT CONTINUE.		No/ 2020-09-23 (33)	Withdrawal of Consent by Participant/ PT CALLED ON 9/23/2020 AND SPOKE COORDINATOR AND STATED HE CHANGED HIS MIND, THE PT ALSO STATED HIS WIFE READ SOME THINGS ABOUT THE TRIAL AND FOR PERSONAL REASON, HE WOULD RATHER NOT CONTINUE.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3512176	2020-08-29	3	ONGOING			No/ 2020-09-30 (33)	Adverse Event/ DUE TO THE SUBJECT'S AE'S OF FATIGUE, HEADACHE, AND INTERMITTENT HIVES THAT BEGAN AFTER THE FIRST INJECTION, SUBJECT WISHED NOT TO GET THE SECOND DOSE OF IP. SHE STILL WISHES TO PARTICIPATE IN STUDY.
US3522042	2020-08-07	1	ONGOING			No/ 2020-08-22 (16)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3522104	2020-08-12	1	No/ 2020-10-12 (62)	Withdrawal of Consent by Participant/ PARTICIPANT EMAILED US STATING THEY WERE WITHDRAWING FROM THE STUDY.		Yes/ 2020-09-10 (30)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3522242	2020-08-20	2	No/ 2020-09-25 (37)	Withdrawal of Consent by Participant/ PARTICIPANT DECIDED TO WITHDRAW AFTER MISSING THEIR SCHEDULED VISIT 2 APPOINTMENT.		No/ 2020-09-25 (37)	Withdrawal of Consent by Participant/ PARTICIPANT TOLD US BY PHONE WHEN CONTACT WAS ATTEMPTED TO RESCHEDULE SECOND APPOINTMENT THAT THEY MISSED THAT THEY WERE WITHDRAWING
US3522297	2020-08-21	2	ONGOING			No/ 2020-09-18 (29)	Due to SARS-CoV-2
US3532020	2020-08-13	2	ONGOING			No/ 2020-09-18 (37)	Adverse Event/ AE #2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3532170	2020-08-27	3	ONGOING			No/ 2020-10-02 (37)	Serious Adverse Event/ SAE #1
US3542043	2020-08-24	2	ONGOING			No/ 2020-10-05 (43)	Due to SARS-CoV-2
US3542090	2020-08-28	3	ONGOING			No/ 2020-10-10 (44)	Adverse Event/ AE #2
US3542168	2020-09-04	3	ONGOING			No/ 2020-10-08 (35)	Physician Decision/ PHYSICIAN WITHHELD DOSE DUE TO HOSPITAL ADMISSIONS FOR PSYCHIATRIC REASONS
US3552087	2020-08-19	2	ONGOING			No/ 2020-09-17 (30)	Adverse Event/ AE #1

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3552103	2020-08-20	2	ONGOING			No/ 2020-09-21 (33)	Adverse Event/ AE #1
US3552107	2020-08-20	2	ONGOING			No/ 2020-09-25 (37)	Other/ SUBJECT IN ILLNESS PERIOD
US3552140	2020-08-22	2	ONGOING			No/ 2020-09-21 (31)	Adverse Event/ AE #2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3552204	2020-08-27	3	ONGOING			No/ 2020-09-25 (30)	Physician Decision/ SUBJECT TRAVELING FOR NEXT 2 WKS; UNABLE TO STAY WITHIN ONE HR OF SITE DURING EDIARY PERIOD; SUBJECT ALSO HAS A SINUS INFECTION AND IS ON PREDNISONE
US3552232	2020-08-29	3	ONGOING			No/ 2020-10-03 (36)	Serious Adverse Event/ SAE #3
US3552273	2020-09-01	3	ONGOING			No/ 2020-09-28 (28)	Adverse Event/ AE #1

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3552331	2020-09-04	3	ONGOING			No/ 2020-10-01 (28)	Serious Adverse Event/ SAE #1
US3552397	2020-09-09	3	No/ 2020-11-16 (68)	Withdrawal of Consent by Participant/ SUBJECT CALLED TO STATE HE IS NO LONGER WILLING TO COME TO THE SITE AND WISHES TO WITHDRAW CONSENT		Yes/ 2020-10-12 (33)	
US3552413	2020-09-11	3	ONGOING			No/ 2020-10-16 (36)	Other/ SUBJECT IN ILLNESS PERIOD

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3552444	2020-09-16	3	ONGOING			No/ 2020-10-14 (29)	Adverse Event/ AE #3
US3562004	2020-08-04	1	No/ 2020-09-21 (49)	Withdrawal of Consent by Participant/ PT DOES NOT WANT TO CONTINUE WITH STUDY AND WITHDREW CONSENT. DID NOT PROVIDE SPECIFIC REASON FOR NOT TO CONTINUE		No/ 2020-09-21 (49)	Withdrawal of Consent by Participant/ PATIENT DOES NOT WANT TO CONTINUE WITH STUDY AND DID NOT PROVIDE SPECIFIC REASON FOR NOT TO CONTINUE

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3562195	2020-09-23	3	No/ 2020-10-21 (29)	Withdrawal of Consent by Participant/ PATIENT DENIED FOR NASAL SWAB AND WITHDREW CONSENT AS CAN NOT DISPSEND VACCINE WITHOUT NASAL SWAB PER PROTOCOL		No/ 2020-10-21 (29)	Withdrawal of Consent by Participant/ PT DOES NOT WANT TO DO NASAL SWAB AND WITHDREW CONSENT

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3562236	2020-10-20	4	No/ 2020-11-19 (31)	Withdrawal of Consent by Participant/ PT DOES NOT WANT TO DO BLOOD DRAW ANYMORE AND SITE CAN NOT DOSE PATIENT WITHOUT BLOOD DRAW AND SWAB. PT WITHDREW CONSENT AND WALKED OUT		No/ 2020-11-19 (31)	Withdrawal of Consent by Participant/ PT DOES NOT WANT TO DO BLOOD DRAW ANYMORE AND SITE CAN NOT DOSE PATIENT WITHOUT BLOOD DRAW AND SWAB. PT WITHDREW CONSENT AND WALKED OUT

* indicates re-screen subjects.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3592005	2020-08-05	1	No/ 2020-08-21 (17)	Withdrawal of Consent by Participant/ SUBJECT DID NOT WANT TO DO E-DIARY		No/ 2020-08-21 (17)	Withdrawal of Consent by Participant/ WITHDREW CONSENT DUE TO NOT WANTING TO DO E-DIARY
US3592078	2020-08-09	1	No/ 2020-08-28 (20)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DUE TO CONFLICTING SCHEDULES FOR RETURN VISITS		No/ 2020-08-20 (12)	Withdrawal of Consent by Participant/ DUE TO CONFLICTING SCHEDULE WITH RETURN APPOINTMENTS
US3592218	2020-08-17	2	No/ 2020-10-15 (60)	Lost to Follow-Up		Yes/ 2020-09-14 (29)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3622012	2020-08-11	1	No/ 2020-11-13 (95)	Withdrawal of Consent by Participant/ PARTICIPANT MOVED OUT OF STATE.		No/ 2020-09-04 (25)	Adverse Event/ AE LOG LINE 1
US3622101	2020-08-28	2	No/ 2020-10-20 (54)	Withdrawal of Consent by Participant		Yes/ 2020-09-26 (30)	
US3622102	2020-08-28	2	No/ 2020-10-19 (53)	Withdrawal of Consent by Participant/ WITHDRAWAL OF CONSENT		Yes/ 2020-09-26 (30)	

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3622145	2020-09-03	3	No/ 2020-09-28 (26)	Withdrawal of Consent by Participant/ PARTICIPANT WITHDREW CONSENT		No/ 2020-09-28 (26)	Withdrawal of Consent by Participant/ PARTICIPANT WITHDREW CONSENT
US3632032	2020-09-01	3	No/ 2020-10-19 (34)	Withdrawal of Consent by Participant/ PARTICIPANT REQUESTED TO WITHDRAW DUE TO HEALTH CHALLENGES AND A NEW JOB, MAKING IT DIFFICULT TO KEEP VISITS/STUDY PROCEDURES.		No/ 2020-10-19 (34)	Withdrawal of Consent by Participant/ PARTICIPANT REQUESTED TO WITHDRAW DUE TO HEALTH CHALLENGES AND A NEW JOB, MAKING IT DIFFICULT TO KEEP VISITS/STUDY PROCEDURES.

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3632080	2020-09-14	3	No/ 2020-10-30 (47)	Withdrawal of Consent by Participant/ THE PARTICIPANT WITHDREW FROM THE STUDY BECAUSE HE IS (b) (6)		Yes/ 2020-10-09 (26)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3662133	2020-09-24	3	ONGOING			No/ 2020-11-13 (51)	Protocol Deviation/ DAY 29 VISIT >2 WEEKS OUT OF WINDOW, PER STUDY TEAM INSTRUCTIONS
US3672013	2020-08-06	1	No/ 2020-09-09 (35)	Withdrawal of Consent by Participant/ PATIENT NO LONGER HAS TIME TO PARTICIPATE		No/ 2020-09-09 (35)	Other/ PATIENT NO LONGER HAS TIME TO PARTICIPATE
US3672053	2020-08-11	2	No/ 2020-09-24 (45)	Lost to Follow-Up		No/ 2020-09-24 (45)	Lost to Follow-Up
US3672097	2020-08-13	2	ONGOING			No/ 2020-09-11 (30)	Adverse Event/ AE#1

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3672151	2020-08-17	2	ONGOING			No/ 2020-08-18 (2)	Adverse Event/ AE 1
US3672169	2020-08-18	2	No/ 2020-11-09 (84)	Lost to Follow-Up		Yes/ 2020-09-16 (30)	
US3672233	2020-08-20	2	ONGOING			No/ 2020-09-22 (34)	Protocol Deviation/ SUBJECT RECEIVED TETANUS VACCINE, MEETS EXCLUSION #9
US3672278	2020-08-24	2	ONGOING			No/ 2020-09-28 (29)	Serious Adverse Event/ AE#1
US3682040	2020-09-01	3	ONGOING			No/ 2020-09-29 (29)	Adverse Event/ AE - #2

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3722223	2020-08-13	2	No/ 2020-10-09 (58)	Lost to Follow-Up		No/ 2020-10-09 (58)	Lost to Follow-Up
US3722328	2020-08-20	2	No/ 2020-10-16 (58)	Lost to Follow-Up		No/ 2020-10-16 (58)	Lost to Follow-Up
US3732061	2020-08-13	2	No/ 2020-10-12 (61)	Withdrawal of Consent by Participant/ SUBJECT CONTACTED SITE (12-OCT-20) INFORMING HE WOULD LIKE TO WITHDRAW CONSENT		Yes/ 2020-09-10 (29)	

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3732085	2020-08-18	2	No/ 2020-10-13 (57)	Withdrawal of Consent by Participant/ SUBJECT DECISION TO WITHDRAW FROM STUDY DUE TO WORK SCHEDULE		Yes/ 2020-09-15 (29)	
US3732111	2020-08-20	2	No/ 2020-09-17 (29)	Withdrawal of Consent by Participant/ SUBJECT WISHES TO NO LONGER PARTICIPATE		No/ 2020-08-20 (1)	Withdrawal of Consent by Participant/ SUBJECT WISHES TO NO LONGER PARTICIPATE

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3732207	2020-08-27	3	No/ 2020-09-24 (29)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER WANTS TO PARTICIPATE DUE TO TOO MANY FOLLOW-UP CALLS/VISITS (SINCE THEY ARE CONFIRMED COVID POSITIVE)		No/ 2020-09-21 (26)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3732258	2020-09-02	3	No/ 2020-09-27 (26)	Withdrawal of Consent by Participant/ NO LONGER WILLING TO PARTICIPATE DUE TO BLOOD/SWAB BEING "UNCOMFORTABLE" AND NOT WILLING TO GIVE BLOOD/SWAB AT ANY FUTURE VISITS. AND NOW UNABLE TO RECEIVE 2ND DOSE (PER SPONSOR)		No/ 2020-09-27 (26)	Withdrawal of Consent by Participant/ NO LONGER WILLING TO PARTICIPATE DUE TO BLOOD/SWAB BEING "UNCOMFORTABLE" AND NOT WILLING TO GIVE BLOOD/SWAB AT ANY FUTURE VISITS. AND NOW UNABLE TO RECEIVE 2ND DOSE (PER SPONSOR)

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3732346	2020-09-15	3	No/ 2020-10-22 (38)	Withdrawal of Consent by Participant/ SUBJECT IS UNWILLING TO FOLLOW-UP WITH SITE FOR THE REMAINDER OF THE STUDY DUE TO ACCEPTING JOB OFFER OUT OF STATE.		Yes/ 2020-10-13 (29)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3732365	2020-09-21	3	No/ 2020-11-13 (54)	Withdrawal of Consent by Participant/ SUBJECT CONTACTED SITE STATING THAT THEY NO LONGER WISH TO PARTICIPATE FOR UNDISCLOSED PERSONAL REASONS		Yes/ 2020-10-19 (29)	

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3742101	2020-08-26	3	No/ 2020-10-28 (64)	Withdrawal of Consent by Participant/ PARTICIPANT STATES HE IS UNABLE TO CONTINUE DUE TO TIME COMMITMENT		No/ 2020-09-30 (36)	Other/ PARTICIPANT OUT OF AREA FOR SEVERAL WEEKS AND WILL NOT BE VACCINATED WITHIN TOLERANCE WINDOW.
US3742164	2020-08-29	3	No/ 2020-09-12 (15)	Withdrawal of Consent by Participant/ MOVING TO (b) (6) IMMEDIATELY		No/ 2020-09-12 (15)	Other/ MOVING TO (b) (6) IMMEDIATELY
US3742253	2020-09-04	3	ONGOING			No/ 2020-10-03 (30)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3742395	2020-09-17	3	ONGOING			No/ 2020-10-07 (21)	Adverse Event/ AE 1
US3742457	2020-09-22	3	No/ 2020-10-27 (36)	Withdrawal of Consent by Participant/ PARTICIPANT STATED THAT HE NO LONGER WANTED TO PARTICIPATE.		No/ 2020-10-27 (36)	Withdrawal of Consent by Participant/ PT NO LONGER WANTED TO REMAIN IN STUDY AND WITHDREW CONSENT TO REMAIN.
US3742477	2020-09-28	3	ONGOING			No/ 2020-10-23 (23)	Due to SARS-CoV-2

* indicates re-screen subjects.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3752053	2020-08-12	2	No/ 2020-09-08 (28)	Withdrawal of Consent by Participant/ SUBJECT IS MOVING OUT OF STATE		No/ 2020-09-08 (28)	Withdrawal of Consent by Participant/ SUBJECT IS MOVING OUT OF STATE
US3752366	2020-09-02	3	ONGOING			No/ 2020-09-08 (7)	Due to SARS-CoV-2
US3772023	2020-08-06	1	No/ 2020-10-15 (71)	Withdrawal of Consent by Participant/ VOLUNTARY W/C NOT DUE TO AN SAE OR AE BUT DUE TO MOVING		Yes/ 2020-09-09 (35)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3772048	2020-08-12	2	No/ 2020-08-27 (16)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT NOT DUE TO AN AE OR SAE		No/ 2020-08-27 (16)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT NOT DUE TO AN AE OR SAE
US3772051	2020-08-12	2	No/ 2020-09-28 (48)	Serious Adverse Event/ USA-US107-2020-MRNA-1273-P301000001 SAE #1		No/ 2020-09-28 (48)	Serious Adverse Event/ USA-US107-2020-MRNA-1273-P301000001 SAE#1
US3772151	2020-08-24	2	ONGOING			No/ 2020-09-22 (30)	Other/ SUBJECT DECLINED SECOND DOSE

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3772177	2020-08-28	3	No/ 2020-11-18 (83)	Withdrawal of Consent by Participant/ THIS SUBJECT REPORTS BEING FRUSTRATED WITH THE SAFETY FOLLOW UP DIARY ENTRIES AND WISHES TO W/C.		Yes/ 2020-09-25 (29)	
US3782073	2020-08-24	2	ONGOING			No/ 2020-09-21 (29)	Physician Decision/ SEE EPIP; HISTORY OF NEW ONSET ANGIOEDEMA
US3792031	2020-08-24	2	No/ 2020-09-28 (36)	Lost to Follow-Up		No/ 2020-09-28 (36)	Lost to Follow-Up

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3802175	2020-09-08	3	ONGOING			No/ 2020-10-09 (32)	Protocol Deviation/ SUBJECT TAKING ACCUTANE AND ADVISED VIA EPIP NOT TO GET SECOND DOSE
US3812083	2020-08-07	1	No/ 2020-11-12 (98)	Withdrawal of Consent by Participant/ SUBJECT REPORTS THAT SHE IS MOVING SOON AND IS NO LONGER INTERESTED IN PARTICIPATING IN THE STUDY.		Yes/ 2020-09-02 (27)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3812125	2020-08-11	1	No/ 2020-10-02 (53)	Lost to Follow-Up		Yes/ 2020-09-11 (32)	
US3812174	2020-08-14	2	ONGOING			No/ 2020-08-14 (1)	Due to SARS-CoV-2
US3812197	2020-08-17	2	ONGOING			No/ 2020-08-17 (1)	Due to SARS-CoV-2
US3812211	2020-08-19	2	No/ 2020-09-24 (37)	Withdrawal of Consent by Participant/ SUBJECT REFUSED TO UNDERGO ANY NASAL SWABBING FOR THE REMAINDER OF THE STUDY		No/ 2020-09-24 (37)	Withdrawal of Consent by Participant/ SUBJECT REFUSED TO UNDERGO ANY NASAL SWABBING FOR THE REMAINDER OF THE STUDY

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3812304	2020-09-01	1	No/ 2020-09-01 (1)	Withdrawal of Consent by Participant/ PER PI, SUBJECT WITHDREW CONSENT "DUE TO ANGER AT BEING ASKED TO PROPERLY MASK WHILE IN THE PUBLIC AREA (WAITING ROOM)"		No/ 2020-09-01 (1)	Withdrawal of Consent by Participant/ PER PI, SUBJECT WITHDREW CONSENT "DUE TO ANGER AT BEING ASKED TO PROPERLY MASK WHILE IN THE PUBLIC AREA (WAITING ROOM)"
US3822006	2020-08-04	1	ONGOING			No/ 2020-09-08 (36)	Adverse Event/ SWELLING UNDER LEFT EYE, AE #1
US3822270	2020-08-26	2	No/ 2020-09-28 (34)	Lost to Follow-Up		No/ 2020-09-28 (34)	Lost to Follow-Up

* indicates re-screen subjects.
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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\l16020101.sas 01DEC2020 04:35

Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3832074	2020-08-04	1	ONGOING			No/ 2020-09-04 (32)	Other/ SUBJECT DID NOT WITHDRAW CONSENT FOR THE STUDY, BUT DID NOT WISH TO RECEIVE SECOND IP DOSE. SUBJECT AGREED TO CONTINUE STUDY PARTICIPATION WITH ALL OTHER PROCEDURES/ASSESSMENTS PER PROTOCOL.

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3852011	2020-08-24	2	No/ 2020-10-22 (60)	Withdrawal of Consent by Participant/ PT CHOSE TO WITHDRAW FROM STUDY AFTER RECEIVING BOTH DOSES. PT FELT THAT BECAUSE OF NO SYMPTOMS AND NEG AB TEST, HE DID NOT NEED TO CONTINUE. PT WAS EDUCATED ON SAFETY AND CHOSE TO WITHDRAW FROM STUDY		Yes/ 2020-09-18 (26)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3852057	2020-08-28	3	No/ 2020-09-28 (32)	Withdrawal of Consent by Participant/ PATIENT MAY HAVE RECEIVED THE WRONG DOSE DUE TO COORDINATOR/PHARMACY ERROR. PATIENT WITHDREW CONSENT BEFORE HER VISIT 2. SHE DID NOT SEE WHY SHE SHOULD CONTINUE IF THE DOSES WERE GOING TO BE DIFFERENT		No/ 2020-08-28 (1)	Withdrawal of Consent by Participant/ PATIENT WANTED TO WITHDRAW FROM STUDY DUE TO MIX UP INTIALLY WITH HER NUMBER AND HER SISTER'S PATINET ID NUMBER.

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\l16020101.sas 01DEC2020 04:35

Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3852079	2020-09-01	3	No/ 2020-10-09 (39)	Lost to Follow-Up		No/ 2020-10-09 (39)	Lost to Follow-Up

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3852130	2020-09-08	3	No/ 2020-09-23 (16)	Withdrawal of Consent by Participant/ SPOKE WITH PATIENT TODAY REGARDING HIS DESIRE TO WITHDRAW FROM THE TRIAL. HE STATED HE FELT IT WAS MORE IMPORTANT TO GET HIS FLU VACCINE INSTEAD OF WAITING THE 14 DAYS POST HIS SECOND COVE VACCINE		No/ 2020-09-08 (1)	Withdrawal of Consent by Participant/ SPOKE WITH PATIENT TODAY REGARDING HIS DESIRE TO WITHDRAW FROM THE TRIAL. HE STATED HE FELT IT WAS MORE IMPORTANT TO GET HIS FLU VACCINE INSTEAD OF WAITING THE 14 DAYS POST HIS SECOND COVE VACCINE

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3862050	2020-08-24	2	ONGOING			No/ 2020-09-01 (9)	Adverse Event/ #01
US3862086	2020-08-28	3	ONGOING			No/ 2020-09-25 (29)	Pregnancy
US3862098	2020-08-31	3	ONGOING			No/ 2020-09-29 (30)	Adverse Event/ AE #1
US3862166	2020-09-10	3	No/ 2020-11-05 (57)	Withdrawal of Consent by Participant/ SUBJECT SUSPECTED THEY RECEIVED PLACEBO AND WOULD NOT LIKE TO CONTINUE.		Yes/ 2020-10-08 (29)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3872088	2020-08-07	1	No/ 2020-09-16 (41)	Withdrawal of Consent by Participant/ STUDY WAS TOO INVOLVED, DOESN'T HAVE THE TIME		No/ 2020-09-16 (41)	Withdrawal of Consent by Participant/ STUDY WAS TOO INVOLVED , DOESN'T HAVE THE TIME
US3872355	2020-08-28	3	No/ 2020-09-24 (28)	Withdrawal of Consent by Participant/ WANTED TO END THIS STUDY BECAUSE HE WAS IN ANOTHER STUDY		No/ 2020-09-24 (28)	Withdrawal of Consent by Participant/ PT SAID HE WANTED TO END , THAT HE WAS IN ANOTHER STUDY

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3902019	2020-09-02	3	ONGOING			No/ 2020-09-30 (29)	Adverse Event/ URTICARIAL RASH ON BUTTOCKS AND BILATERAL AXILLA
US3902064	2020-09-10	3	ONGOING			No/ 2020-09-15 (6)	Adverse Event/ SYMPTOMATIC COVID-19
US3912125	2020-09-08	3	ONGOING			No/ 2020-10-12 (35)	Physician Decision/ UNABLE TO COLLECT LAB SAMPLES
US3912241	2020-10-12	4	ONGOING			No/ 2020-11-04 (24)	Serious Adverse Event/ PULMONARY EMBOLISM, LLL

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3932147	2020-09-16	3	ONGOING			No/ 2020-10-05 (20)	Serious Adverse Event/ SAE OF WORSENING CHF AND ALSO LEADING TO EXACERBATED COPD.
US3942023	2020-08-28	3	No/ 2020-10-29 (63)	Lost to Follow-Up		No/ 2020-10-29 (63)	Lost to Follow-Up
US3942044	2020-09-02	3	ONGOING			No/ 2020-09-25 (24)	Due to SARS-CoV-2
US3942079	2020-09-08	3	ONGOING			No/ 2020-09-22 (15)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3942115	2020-09-17	3	No/ 2020-11-19 (57)	Physician Decision/ VULNERABLE POPULATION		Yes/ 2020-10-23 (30)	
US3942127	2020-09-21	3	No/ 2020-11-16 (57)	Lost to Follow-Up		No/ 2020-11-16 (57)	Lost to Follow-Up
US3942129	2020-09-22	3	No/ 2020-11-16 (56)	Lost to Follow-Up		No/ 2020-11-16 (56)	Lost to Follow-Up
US3952033	2020-09-02	2	ONGOING			No/ 2020-10-06 (35)	Adverse Event/ COVID-19 POSITIVE

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3982004	2020-08-24	2	No/ 2020-10-02 (36)	Withdrawal of Consent by Participant/ CLAIMED HE WILL NO LONGER BE ABLE TO PARTICIPATE.		No/ 2020-10-02 (36)	Withdrawal of Consent by Participant/ CLAIMED HE WILL NO LONGER BE ABLE TO PARTICIPATE.
US3982021	2020-08-27	3	No/ 2020-10-26 (61)	Withdrawal of Consent by Participant/ PARTICIPA DECISION.		No/ 2020-10-26 (61)	Withdrawal of Consent by Participant/ PARTICIPANT DECISION.
US3982120	2020-09-07	3	No/ 2020-10-05 (29)	Lost to Follow-Up		Yes/ 2020-10-05 (29)	
US3982175	2020-09-15	3	No/ 2020-09-15 (1)	Lost to Follow-Up		No/ 2020-09-15 (1)	Lost to Follow-Up

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3982245	2020-09-28	3	No/ 2020-10-08 (11)	Other/ SUBJECT WITHDREW PARTICIPATION		No/ 2020-10-08 (11)	Other/ SUBJECT WITHDREW PARTICIPATION

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3012053	2020-08-06	2	No/ 2020-09-03 (29)	Physician Decision/ SUBJECT IS NOT MENTALLY STABLE, PROVIDED INCORRECT INFORMATION		No/ 2020-09-03 (29)	Physician Decision/ SUBJECT IS NOT STABLE, PROVIDED INCORRECT INFORMATION
US3012087	2020-08-10	2	ONGOING			No/ 2020-09-07 (29)	Lost to Follow-Up
US3012150	2020-08-14	2	ONGOING			No/ 2020-10-14 (62)	Protocol Deviation/ OBTAINED FLU SHOT

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3012288	2020-09-10	3	No/ 2020-11-10 (62)	Withdrawal of Consent by Participant/ SUBJECT REQUESTED TO BE UNBLINDED TO STUDY TREATMENT. SITE INFORMED SUBJECT THAT WAS NOT POSSIBLE AT THIS STAGE IN THE STUDY AND SUBJECT ENDED STUDY PARTICIPATION DUE TO THIS.		Yes/ 2020-10-15 (36)	
US3022021	2020-07-29	1	ONGOING			No/ 2020-09-28 (62)	Adverse Event/ #1 DUE TO AE

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3022031	2020-07-27	1	ONGOING			No/ 2020-09-29 (65)	Serious Adverse Event/ #1
US3022166	2020-08-17	2	No/ 2020-08-31 (15)	Withdrawal of Consent by Participant/ SUBJECT STATES THAT SHE DOESN'T WANT TO PARTICIPATE ANYMORE.		No/ 2020-08-31 (15)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT
US3032093	2020-08-05	1	No/ 2020-11-13 (101)	Lost to Follow-Up		Yes/ 2020-09-02 (29)	
US3032126	2020-08-06	1	No/ 2020-11-05 (92)	Lost to Follow-Up		No/ 2020-11-05 (92)	Lost to Follow-Up

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3032297	2020-08-21	2	No/ 2020-10-23 (64)	Withdrawal of Consent by Participant/ MOVED OUT OF STATE, SUBJECT WILL NOT BE ABLE TO COMPLY WITH STUDY VISITS. SUBJECT STATED THE MOVE WAS NOT PLANNED.		Yes/ 2020-09-18 (29)	
US3032305	2020-08-21	2	ONGOING			No/ 2020-09-08 (19)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3032313	2020-08-21	2	No/ 2020-10-01 (42)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DUE TO UNFORESEEN ISSUES		No/ 2020-10-01 (42)	Withdrawal of Consent by Participant/ DUE TO UNFORESEEN HEALTH ISSUES. SUBJECT DECLINED TO SIGN RELEASE FOR MEDICAL RECORDS AND DENIED COMING TO STUDY SITE FOR END OF STUDY VISIT.
US3042032	2020-07-29	1	No/ 2020-08-27 (30)	Adverse Event/ AE 1		No/ 2020-08-27 (30)	Adverse Event/ AE 1- CHRONIC DYSPNEA

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3042092	2020-08-06	1	No/ 2020-11-05 (92)	Withdrawal of Consent by Participant/ SUBJECT CALLED AND WITHDREW FROM STUDY; STATING THEY NO LONGER ARE ABLE TO COMMIT TIME TO VISITS AND FOLLOW UPS.		Yes/ 2020-09-10 (36)	

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3042190	2020-08-13	2	No/ 2020-09-17 (36)	Physician Decision/ DUE TO PATIENTS SAE OF MULTIPLE PULMONARY EMBOLI DIAGNOSIS, THE PRIMARY INVESTIGATOR DECIDED FOR THE SAFETY OF THE PATIENT TO DISCONTINUE THEM FROM THE STUDY.		No/ 2020-09-17 (36)	Physician Decision/ DUE TO PATIENTS SAE OF MULTIPLE PULMONARY EMBOLI DIAGNOSIS, THE PRIMARY INVESTIGATOR DECIDED FOR THE SAFETY OF THE PATIENT TO DISCONTINUE THEM FROM THE STUDY.
US3042192	2020-08-14	2	No/ 2020-09-14 (32)	Adverse Event/ AE 1- ELEVATED LIVER ENZYMES		No/ 2020-09-14 (32)	Adverse Event/ AE1- ELEVATED LIVER ENZYMES

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3042249	2020-08-19	2	No/ 2020-09-03 (16)	Withdrawal of Consent by Participant/ SUBJECT STATES THEIR PSYCHIATRIST ADVISED THEM TO DISCONTINUE THE STUDY. SUBJECT WITHDRAW FROM THE STUDY.		No/ 2020-09-03 (16)	Withdrawal of Consent by Participant/ SUBJECT STATES THEIR PSYCHIATRIST ADVISED THEM TO DISCONTINUE THE STUDY. SUBJECT WITHDRAW FROM THE STUDY.
US3062103	2020-08-05	1	No/ 2020-08-31 (27)	Withdrawal of Consent by Participant/ TOO MUCH HAPPENING IN PERSONAL LIFE		No/ 2020-08-31 (27)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW FOR REASON OF "TOO MUCH HAPPENING IN PERSONAL LIFE".

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3082051	2020-08-18	2	No/ 2020-09-08 (22)	Serious Adverse Event/ SAE #1		No/ 2020-09-08 (22)	Serious Adverse Event/ SAE#1
US3082151	2020-08-29	3	No/ 2020-09-01 (4)	Withdrawal of Consent by Participant/ SUBJECT DOES NOT WISH TO ATTEND ANY FUTURE STUDY VISITS.		No/ 2020-09-01 (4)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT AND STATED SHE DOES NOT INTEND TO RETURN FOR ANY FUTURE STUDY VISITS.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3092119	2020-08-12	2	No/ 2020-09-24 (44)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT-CONFIRMED NOT DUE TO AE		No/ 2020-09-24 (44)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3102086	2020-08-03	1	No/ 2020-08-13 (11)	Withdrawal of Consent by Participant/ PARTICIPANT REPORTED AES (DOCUMENTED IN AE SECTION) AND REFUSED TO DO AN ILLNESS VISIT (IN-CLINIC OR AT-HOME). UPON FURTHER CONTACT, PARTICIPANT WITHDREW CONSENT AND DROPPED OUT OF THE STUDY.		No/ 2020-08-13 (11)	Withdrawal of Consent by Participant/ PARTICIPANT REPORTED AES (DOCUMENTED IN AE SECTION) AND REFUSED TO DO AN ILLNESS VISIT (IN-CLINIC OR AT-HOME). UPON FURTHER CONTACT, PARTICIPANT WITHDREW CONSENT AND DROPPED OUT OF THE STUDY.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3102156	2020-08-10	2	No/ 2020-09-29 (51)	Withdrawal of Consent by Participant/ SUBJECT STATED HE IS MOVING OUT OF STATE		Yes/ 2020-09-04 (26)	
US3102183	2020-08-11	2	No/ 2020-09-14 (35)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DUE TO NOT WANTING TO RECEIVE VACCINATION TWO, DUE TO REACTIONS EXPERIENCED WHEN RECEIVED VACCINATION ONE.		No/ 2020-09-14 (35)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DUE TO NOT WANTING TO RECEIVE VACCINATION TWO, DUE TO REACTIONS EXPERIENCED WHEN RECEIVED VACCINATION ONE.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3112122	2020-08-05	1	No/ 2020-08-24 (20)	Protocol Deviation/ ADMITTED TO ALCOHOLISM, PT ADVISED HE IS NOT A GOOD CANDIDATE FOR STUDY. HAS BEEN NON COMPLIANT AND UNABLE TO GIVE AN ACCURATE ACCOUNT OF SYMPTOMS, SOUNDS CONFUSED. BECAME UPSET AND VERBALLY ABUSIVE			

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\l16020101.sas 01DEC2020 04:35

Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3112282	2020-08-17	2	No/ 2020-08-26 (10)	Withdrawal of Consent by Participant/ STIPENDS ARE TAXABLE INCOME		No/ 2020-08-26 (10)	Withdrawal of Consent by Participant/ STIPEND IS TAXABLE INCOME. SUBJECT DOES NOT WANT INCOME THAT IS TAXABLE
US3122010	2020-07-27	1	ONGOING			No/ 2020-08-18 (23)	Serious Adverse Event/ 1

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3132016	2020-08-14	2	No/ 2020-09-18 (36)	Withdrawal of Consent by Participant/ PT HAD ANTIBODY TESTING DONE AND REQUESTED TO WITHDRAWAL CONSENT.		No/ 2020-09-18 (36)	Withdrawal of Consent by Participant/ SUBJECT HAD AN ANTIBODY TEST AND TESTED NEGATIVE.
US3142165	2020-08-08	1	No/ 2020-09-08 (32)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW FOR PERSONAL REASONS		No/ 2020-09-08 (32)	Withdrawal of Consent by Participant/ SUBJECT VERBALLY WITHDREW CONSENT PRIOR TO VISIT DAY 29 FOR PERSONAL REASONS

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3162078	2020-08-07	1	ONGOING			No/ 2020-08-18 (12)	Due to SARS-CoV-2
US3172008	2020-08-07	1	ONGOING			No/ 2020-09-12 (37)	Other/ MISSED VISIT DAY 29
US3172031	2020-08-11	1	ONGOING			No/ 2020-09-16 (37)	Other/ MISSED VISIT.
US3172039	2020-08-11	1	ONGOING			No/ 2020-09-16 (37)	Other/ MISSED VISIT.
US3172065	2020-08-12	1	ONGOING			No/ 2020-09-17 (37)	Other/ MISSED VISIT.
US3172112	2020-08-14	1	ONGOING			No/ 2020-09-19 (37)	Other/ MISSED VISIT.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172121	2020-08-14	1	No/ 2020-09-10 (28)	Withdrawal of Consent by Participant/ NO LONGER WANTS TO PARTICIPATE		No/ 2020-09-10 (28)	Withdrawal of Consent by Participant/ NO LONGER WANTS TO PARTICIPATE
US3172149	2020-08-17	1	ONGOING			No/ 2020-09-22 (37)	Other/ SUBJECT MISSED DAY 29 VISIT.
US3172161	2020-08-17	1	ONGOING			No/ 2020-09-22 (37)	Other/ MISSED VISIT.
US3172164	2020-08-18	1	ONGOING			No/ 2020-09-23 (37)	Other/ MISSED VISIT.
US3172167	2020-08-18	1	ONGOING			No/ 2020-09-23 (37)	Other/ MISSED VISIT.

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172174	2020-08-18	1	ONGOING			No/ 2020-09-23 (37)	Other/ MISSED VISIT.
US3172186	2020-08-18	1	No/ 2020-10-20 (64)	Withdrawal of Consent by Participant		Yes/ 2020-09-15 (29)	
US3172217	2020-08-19	1	ONGOING			No/ 2020-09-24 (37)	Other/ MISSED VISIT.
US3172219	2020-08-19	1	ONGOING			No/ 2020-09-24 (37)	Other/ MISSED VISIT
US3172225	2020-08-19	1	ONGOING			No/ 2020-09-24 (37)	Other/ MISSED VISIT

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172238	2020-08-20	1	ONGOING			No/ 2020-09-17 (29)	Withdrawal of Consent by Participant/ DID NOT WANT TO WAIT
US3172246	2020-08-20	1	No/ 2020-10-01 (43)	Withdrawal of Consent by Participant/ MOVED OUT OF TOWN		No/ 2020-10-01 (43)	Withdrawal of Consent by Participant/ SUBJECT MOVED OUT OF TOWN
US3172249	2020-08-20	1	ONGOING			No/ 2020-09-25 (37)	Other/ SKIPPED VISIT
US3172265	2020-08-21	1	ONGOING			No/ 2020-08-24 (4)	Adverse Event/ A/E #1.

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172290	2020-08-24	2	ONGOING			No/ 2020-09-28 (36)	Other/ MISSED VISIT DAY 29
US3172360	2020-08-27	3	ONGOING			No/ 2020-09-22 (27)	Adverse Event/ A/E #1
US3172366	2020-08-27	3	ONGOING			No/ 2020-10-02 (37)	Other/ MISSED VISIT
US3192329	2020-08-17	1	No/ 2020-10-14 (53)	Lost to Follow-Up		No/ 2020-08-23 (1)	Lost to Follow-Up
US3202106	2020-08-10	1	No/ 2020-09-16 (38)	Withdrawal of Consent by Participant/ SUBJECT OPTED OUT OF GETTING SECOND DOSE		No/ 2020-09-16 (38)	Withdrawal of Consent by Participant/ SUBJECT OPTED OUT OF STUDY, DECIDED NOT TO GET SECOND DOSE OF VACCINE

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202112	2020-08-10	1	No/ 2020-09-29 (51)	Withdrawal of Consent by Participant/ SUBJECT MOVED TO ANOTHER STATE AND IS NOT INTERESTED IN CONTINUED F/UP		No/ 2020-09-29 (51)	Withdrawal of Consent by Participant/ SUBJECT MOVED TO ANOTHER STATE AND IS NOT INTERESTED IN CONTINUED F/UP

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202173	2020-08-13	2	No/ 2020-10-16 (65)	Physician Decision/ SUBJECT IS NONCOMPLIANT WITH VISIT SCHEDULES OR ACCURATE REPORTING OF HEALTH		No/ 2020-10-15 (64)	Protocol Deviation/ SUBJECT MISSED DAY 29 VISIT AND WAS OUT OF WINDOW BY THE TIME WE REACHED HER AND WE'RE NOT ABLE TO CONFIRM APPROPRIATENESS FOR CONTINUING DUE TO APPARENT PSYCHIATRIC ISSUES.

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202176	2020-08-14	2	No/ 2020-10-02 (50)	Withdrawal of Consent by Participant/ MULTIPLE STRESSORS IN PERSONAL LIFE --UNABLE TO GET SECOND DOSE AND HAS "TOO MUCH STRESS" TO WORRY ABOUT CONTINUING IN STUDY		No/ 2020-09-11 (29)	Other/ SUBJECT UNABLE TO COMPLETE DAY 29 WITHIN WINDOW
US3202203	2020-08-15	2	ONGOING			No/ 2020-10-01 (48)	Other/ SUBJECT WITHDREW FROM DOSING BUT AGREED TO CONTINUE IN STUDY

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202263	2020-08-19	2	No/ 2020-10-19 (62)	Withdrawal of Consent by Participant/ SUBJECT GAVE NO REASON--JUST STATED THAT SHE WAS WITHDRAWING FROM STUDY.		No/ 2020-10-19 (62)	Withdrawal of Consent by Participant/ SUBJECT DID NOT GIVE REASON--SHE RETURNED CALLS BY SC BUT TOLD RECEPTIONIST TO INFORM ME THAT SHE WAS WITHDRAWING FROM THE STUDY THEN HUNG UP.
US3202307	2020-08-24	3	No/ 2020-09-22 (30)	Physician Decision/ SUBJECT WAS NOT FOLLOWING CONTRACEPTION GUIDELINES		No/ 2020-09-22 (30)	Physician Decision/ SUBJECT WAS NOT FOLLOWING CONTRACEPTION GUIDELINES.

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202358	2020-08-28	3	No/ 2020-11-20 (85)	Lost to Follow-Up		No/ 2020-11-20 (85)	Lost to Follow-Up
US3202383	2020-09-02	3	ONGOING			No/ 2020-10-30 (59)	Protocol Deviation/ SUBJECT TOO FAR OUT OF WINDOW FOR DOSE 2 DUE TO TRAVELLING FOR FUNERAL AND THEN MULTIPLE RESCHEDULED APPOINTMENTS
US3202399	2020-09-04	3	No/ 2020-11-18 (76)	Lost to Follow-Up		No/ 2020-11-18 (76)	Other/ SUBJECT NOT ABLE TO DOSE AT DAY 29 AND NEVER RETURNED FOR R/S VISITS

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3212182	2020-08-14	2	ONGOING			No/ 2020-09-11 (29)	Pregnancy
US3212398	2020-09-11	3	No/ 2020-10-13 (33)	Withdrawal of Consent by Participant/ SUBJECT CALLED TO WITHDRAW CONSENT FROM THE STUDY. HE WAS OFFERED A SAFETY VISIT AND EVERY EFFORT WAS MADE TO KEEP SUBJECT IN THE STUDY, HOWEVER HE DID NOT WISH TO PROCEED ANY FURTHER.		Yes/ 2020-10-08 (28)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222085	2020-08-11	1	No/ 2020-09-07 (28)	Withdrawal of Consent by Participant/ PT WITHDREW CONSENT DUE TO MEDICAL REASONS UNRELATED TO THIS STUDY		No/ 2020-09-07 (28)	Withdrawal of Consent by Participant/ PT STATED THAT HE HAD TO W/D FOR MEDICAL REASONS UNRELATED TO THIS STUDY.
US3222096	2020-08-11	1	No/ 2020-09-15 (36)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT ON FAMILY ADVISE.		No/ 2020-09-15 (36)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT BASED ON FAMILY ADVICE.

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3222433	2020-09-01	3	No/ 2020-10-01 (31)	Withdrawal of Consent by Participant/ TOO MUCH OF A COMITMENT		No/ 2020-10-01 (31)	Withdrawal of Consent by Participant/ TOOMUCH OF A COMMITMENT
US3222572	2020-09-10	3	No/ 2020-11-12 (64)	Withdrawal of Consent by Participant/ SUBJECT W/D CONSENT DUE TO PERSONAL ISSUES.		Yes/ 2020-10-15 (36)	
US3222627	2020-09-21	3	No/ 2020-11-18 (59)	Lost to Follow-Up		Yes/ 2020-10-19 (29)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3232021	2020-08-10	1	ONGOING			No/ 2020-09-09 (31)	Physician Decision/ SUBJECT ATTRIBUTING WORSENING FINGER JOINT PAIN TO IP DESPITE DIAGNOSIS OF OSTEOARTHRITIS
US3242288	2020-09-03	3	ONGOING			No/ 2020-09-14 (12)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3242370	2020-09-23	3	No/ 2020-10-19 (27)	Serious Adverse Event/ WORSENING OF SCHIZOAFFECTIVE DISORDER, SUBJECT IS UNSTABLE AND PI NOT WILLING TO UPSET SUBJECT OR PUT STAFF AT RISK		No/ 2020-10-19 (27)	Serious Adverse Event/ SAE #1
US3252356	2020-08-28	3	No/ 2020-09-21 (25)	Other/ PATIENT HAS BEEN INCARCERATED		No/ 2020-09-21 (25)	Other/ PATIENT IS INCARCERATED

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3262004	2020-07-27	1	No/ 2020-09-28 (64)	Other/ (b) (6)		No/ 2020-09-28 (64)	Other/ (b) (6)

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3262034	2020-07-29	1	No/ 2020-09-28 (62)	Other/ SUBJECT IS UNABLE TO KEEP HER SAFETY APPOINTMENTS RECENTLY MOVED TO OTHER CITY		Yes/ 2020-08-27 (30)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3262035	2020-07-29	1	No/ 2020-08-26 (29)	Physician Decision/ PATIENT WAS HARASSING AND THREATENING THE SITE WHEN WE TOLD HER THE CREDIT CARD PAYMENT WOULD BE GIVEN AS SOON AS THE CARDS CAME IN.PATIENT CALLED DAILY AND THREATENED STAFF, PI AS WOULD NOT WAIT.		No/ 2020-08-26 (29)	Physician Decision/ SPOKE TO STUDY TEAM ABOUT STAFF SAFETY CONCERNS OVER THIS PATIENT, AND AGREED TO DISCONTINUE DUE TO THREATENING AND HARASSING BEHAVIOR. DID NOT WANT TO RISK OUR SAFETY OVER THIS UNBALANCED PATIENT.

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3262074	2020-08-03	1	No/ 2020-11-10 (100)	Physician Decision/ DUE TO NUMEROUS ABUSIVE CALLS WHERE PT YELLS, ASK FOR REIMBURSEMENT NOT BASED ON THE PROTOCOL JUST BECAUSE HE WANTS. WE ARE DISCONTINUING THE PT HE IS NOT SAFE TO DEAL WITH AS WE DONT KNOW HOW HIS ABU		Yes/ 2020-09-01 (30)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3292252	2020-08-20	2	No/ 2020-09-28 (40)	Withdrawal of Consent by Participant/ PT VERBALLY W/D CONSENT. HAD SAFETY CONCERNS.		No/ 2020-09-28 (40)	Withdrawal of Consent by Participant/ PT VERBALLY W/D CONSENT. HAD SAFETY CONCERNS.
US3302123	2020-08-10	1	No/ 2020-09-04 (26)	Withdrawal of Consent by Participant/ AE		No/ 2020-09-04 (26)	Withdrawal of Consent by Participant/ AE

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3302203	2020-08-14	2	No/ 2020-09-21 (39)	Withdrawal of Consent by Participant/ SUBJECT STATES HE IS NO LONGER ABLE TO PARTICIPATE IN TRIAL.		No/ 2020-09-21 (39)	Withdrawal of Consent by Participant/ SUBJECT STATES HE IS NO LONGER ABLE TO PARTICIPATE IN TRIAL.
US3302261	2020-08-18	2	No/ 2020-09-22 (36)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER ABLE TO TAKE PART IN TRIAL DUE TO HAVING TO CARE FOR HIS MOTHER		No/ 2020-09-22 (36)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER ABLE TO TAKE PART IN TRIAL DUE TO HAVING TO CARE FOR HIS MOTHER

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3302263	2020-08-18	2	No/ 2020-11-02 (77)	Withdrawal of Consent by Participant/ SUBJECT DECISION DUE TO PERSONAL CONFLICTS		Yes/ 2020-09-15 (29)	
US3302377	2020-08-26	3	No/ 2020-11-04 (71)	Other/ SUBJECT DECIDED TO DROP DUE TO WORK SCHEDULE CONFLICT		Yes/ 2020-09-24 (30)	

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3302386	2020-08-26	3	No/ 2020-09-21 (27)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER INTERESTED DUE TO PERSONAL REASONS		No/ 2020-09-21 (27)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER INTERESTED DUE TO PERSONAL REASONS
US3302387	2020-08-26	3	No/ 2020-09-21 (27)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER INTERESTED DUE TO PERSONAL REASONS		No/ 2020-09-21 (27)	Withdrawal of Consent by Participant/ SUBJECT NO LONGER INTERESTED DUE TO PERSONAL REASONS.

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3302441	2020-08-28	3	No/ 2020-09-28 (32)	Withdrawal of Consent by Participant/ SUBJECT UNABLE TO CONTINUE DUE TO WORK SCHEDULE		No/ 2020-09-28 (32)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW DUE TO WORK SCHEDULE
US3312116	2020-08-17	2	No/ 2020-10-15 (60)	Withdrawal of Consent by Participant/ SUBJECT MOVED OUT OF STATE AND DOES NOT WISH TO CONTINUE FURTHER STUDY PROCEDURES OR VISITS		No/ 2020-10-15 (60)	Withdrawal of Consent by Participant/ SUBJECT MOVED OUT OF STATE AND DOES NOT WISH TO CONTINUE FURTHER STUDY PROCEDURES OR VISITS

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3312191	2020-08-20	2	No/ 2020-10-02 (44)	Withdrawal of Consent by Participant/ SUBJECT MOVED OUT OF STATE. SUBJECT DECLINED OPTION TO CONTINUE SAFETY PHONE CALLS, AND DECLINED REMAINING IN STUDY.		Yes/ 2020-09-17 (29)	
US3312197	2020-08-20	2	ONGOING			No/ 2020-09-17 (29)	Adverse Event/ AE#2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3312246	2020-08-24	2	No/ 2020-11-06 (75)	Withdrawal of Consent by Participant/ SUBJECT STATES THE WEEKLY EDIARY'S HAVE BECOME TOO MUCH FOR HIM TO KEEP UP WITH, THEY WERE CAUSING TOO MUCH INTERFERENCE WITH PERSONAL LIFE.		Yes/ 2020-09-21 (29)	
US3312338	2020-08-27	3	No/ 2020-09-18 (23)	Lost to Follow-Up		No/ 2020-09-18 (23)	Lost to Follow-Up

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3312537	2020-09-08	3	No/ 2020-09-29 (22)	Lost to Follow-Up		No/ 2020-09-29 (22)	Lost to Follow-Up

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3322026	2020-08-18	2	No/ 2020-10-28 (72)	Withdrawal of Consent by Participant/ SUBJECT DID NOT SHOW TO HIS VISIT 3 APPOINTMENT ON 2 OCCASIONS. SITE REACHED OUT TO SUBJECT ONE MORE TIME TO RE-SCHEDULE HIS APPOINTMENT AND SUBJECT EXPRESSED HE WITHDREW CONSENT.		Yes/ 2020-09-15 (29)	

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3322121	2020-08-27	3	No/ 2020-10-05 (40)	Withdrawal of Consent by Participant/ PATIENT WAS NO LONGER INTERESTED IN PARTICIPATING.		No/ 2020-10-05 (40)	Withdrawal of Consent by Participant/ PATIENT WAS NO LONGER INTERESTED IN PARTICIPATING.
US3322174	2020-09-01	3	No/ 2020-09-10 (10)	Withdrawal of Consent by Participant/ PATIENT WAS NO LONGER INTERESTED IN PARTICIPATING IN THE STUDY.		No/ 2020-09-10 (10)	Withdrawal of Consent by Participant/ PATIENT WAS NO LONGER INTERESTED IN PARTICIPATING IN THE STUDY.

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3342018	2020-08-11	2	No/ 2020-10-08 (57)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT VIA PHONE ON 08OCT2020		No/ 2020-10-08 (57)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT VIA PHONE ON 08OCT2020

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3342119	2020-08-19	2	No/ 2020-09-21 (34)	Withdrawal of Consent by Participant/ SUBJECT CAME IN FOR SCHEDULED VISIT OF VACCINATION 2 ON 21SEP2020 AND VERBALIZED SHE WOULD LIKE TO WITHDRAW AND WITHDRAW CONSENT		No/ 2020-09-21 (34)	Withdrawal of Consent by Participant/ SUBJECT CAME IN FOR SCHEDULED VISIT OF VACCINATION 2 ON 21SEP2020 AND VERBALIZED SHE WOULD LIKE TO WITHDRAW AND WITHDRAW CONSENT

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3342205	2020-09-08	3	No/ 2020-11-06 (60)	Withdrawal of Consent by Participant/ SUBJECT CALLED SITE AND EXPRESSED THAT HE WOULD LIKE TO WITHDRAW FROM STUDY		No/ 2020-11-06 (60)	Withdrawal of Consent by Participant/ SUBJECT CALLED SITE AND EXPRESSED THAT HE WOULD LIKE TO WITHDRAW FROM STUDY
US3342239	2020-09-10	3	No/ 2020-11-11 (63)	Lost to Follow-Up		No/ 2020-10-13 (34)	Adverse Event/ AE 1
US3342272	2020-09-18	3	No/ 2020-10-13 (26)	Physician Decision/ PI CHOSE TO WITHDRAW SUBJECT FROM STUDY		No/ 2020-10-13 (26)	Physician Decision/ PI CHOSE TO WITHDRAW SUBJECT FROM STUDY

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3342286	2020-09-26	3	ONGOING			No/ 2020-10-21 (26)	Adverse Event/ AE: HYPERTENSION, UNSPECIFIED.
US3352017	2020-08-04	1	No/ 2020-11-05 (94)	Lost to Follow-Up		Yes/ 2020-09-01 (29)	
US3352101	2020-08-18	2	No/ 2020-09-14 (28)	Physician Decision/ SUBJECT NON COMPLIANT. AS PER PI DECISION SUBJECT WAS WITHDRAWN FROM THE STUDY.		No/ 2020-09-14 (28)	Physician Decision/ SUBJECT NON COMPLIANT AND WITHDRAWN FROM STUDY PER PI DECISION.

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3352358	2020-09-10	3	ONGOING			No/ 2020-10-15 (36)	Withdrawal of Consent by Participant/ SUBJECT DID NOT FEEL COMFORTABLE RECEIVING SECOND VACCINATION.
US3352525	2020-10-08	4	No/ 2020-11-06 (30)	Withdrawal of Consent by Participant/ THE SUBJECT STATES SHE STARTED A NEW JOB AND WON'T BE ABLE TO CONTINUE WITH THE STUDY.		No/ 2020-11-06 (30)	Withdrawal of Consent by Participant/ THE SUBJECT STATES SHE STARTED A NEW JOB AND WON'T BE ABLE TO CONTINUE WITH THE STUDY.

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3362023	2020-08-03	1	ONGOING			No/ 2020-08-03 (1)	Adverse Event/ AE1
US3362124	2020-08-13	2	ONGOING			No/ 2020-08-21 (9)	Due to SARS-CoV-2
US3362244	2020-08-24	2	ONGOING			No/ 2020-09-23 (31)	Adverse Event/ AE ID 1

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3362289	2020-09-26	3	No/ 2020-11-13 (49)	Withdrawal of Consent by Participant/ PATIENT CONTACTED SITE ON 13NOV2020 TO WITHDRAW HIS PARTICIPATION IN STUDY DUE TO INABILITY TO COMPLY WITH STUDY SCHEDULE AND VISITS.		No/ 2020-11-13 (49)	Withdrawal of Consent by Participant/ PATIENT CONTACTED SITE ON 13NOV2020 TO WITHDRAW HIS PARTICIPATION IN STUDY DUE TO INABILITY TO COMPLY WITH STUDY SCHEDULE AND VISITS.

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3372123	2020-08-14	2	No/ 2020-11-04 (83)	Withdrawal of Consent by Participant/ SUBJECT HAS DEVELOPED CHRONIC KIDNEY DISEASE AND NO LONGER FEELS THEY CAN CONTINUE		Yes/ 2020-09-14 (32)	
US3372306	2020-09-01	3	No/ 2020-09-30 (30)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT		Yes/ 2020-09-30 (30)	

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3392218	2020-09-10	3	No/ 2020-10-14 (35)	Other/ SUBJECT INCARCERATED WITH NO PLANS OF RELEASE.		No/ 2020-10-14 (35)	Other/ SUBJECT INCARCERATED WITH NO PLANS OF RELEASE.
US3392278	2020-09-14	3	No/ 2020-11-11 (59)	Withdrawal of Consent by Participant/ PATIENT DECISION TO QUIT. (DATA CORRECT)			

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3402081	2020-07-29	1	No/ 2020-09-04 (38)	Withdrawal of Consent by Participant/ SUBJECT WAS BEING PLACED IN AN INPATIENT PSYCHIATRIC FACILITY BY (b) (6) AND COULD NO LONGER DO WHAT WAS BEING ASKED OF HER IN THE STUDY.		Yes/ 2020-08-26 (29)	
US3402361	2020-08-15	2	No/ 2020-09-05 (22)	Other/ SUBJECT MOVED OUT OF STATE		No/ 2020-09-05 (22)	Other/ SUBJECT MOVED OUT OF STATE

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3402443	2020-09-09	2	No/ 2020-10-02 (24)	Lost to Follow-Up		No/ 2020-10-02 (24)	Lost to Follow-Up
US3412101	2020-08-03	1	No/ 2020-09-25 (54)	Lost to Follow-Up		No/ 2020-09-22 (51)	Lost to Follow-Up
US3412126	2020-08-04	1	ONGOING			No/ 2020-11-18 (107)	Other/ PATIENTS DECISION TO NOT COME IN FOR SECOND INJECTION AND ALSO NOT FOLLOWING ANY PROTOCOL REQUIREMENTS
US3412129	2020-08-05	1	ONGOING			No/ 2020-08-20 (16)	Due to SARS-CoV-2

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3412172	2020-08-07	1	No/ 2020-10-26 (81)	Lost to Follow-Up		No/ 2020-10-26 (81)	Lost to Follow-Up
US3432334	2020-08-28	3	ONGOING			No/ 2020-09-26 (30)	Due to SARS-CoV-2
US3442087	2020-08-25	3	ONGOING			No/ 2020-09-28 (35)	Withdrawal of Consent by Participant/ SUBJECT DID NOT LIKE SOLICITED REACTIONS CAUSED BY THE VACCINE AND "DOES NOT TRUST" THE 2ND DOSE.

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3442165	2020-09-15	3	ONGOING			No/ 2020-09-15 (1)	Withdrawal of Consent by Participant/ PHYSICIAN DECISION
US3452105	2020-08-01	1	No/ 2020-09-29 (60)	Withdrawal of Consent by Participant/ THE PT IS WITHDRAWING CONSENT DUE TO HER WORK SCHEDULE.		Yes/ 2020-08-29 (29)	
US3452334	2020-08-24	2	ONGOING			No/ 2020-09-23 (31)	Physician Decision/ SUBJECT VERY DEHYDRATED

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3452363	2020-09-15	3	No/ 2020-09-25 (11)	Withdrawal of Consent by Participant/ SUBJECT ASKED TO BE W/D FROM STUDY		No/ 2020-09-25 (11)	Withdrawal of Consent by Participant/ SUBJECT ASKED TO BE WITHDRAWN FORM STUDY
US3452377	2020-09-22	3	No/ 2020-11-17 (57)	Lost to Follow-Up		No/ 2020-11-17 (57)	Lost to Follow-Up
US3452378	2020-09-22	3	No/ 2020-11-17 (57)	Lost to Follow-Up		No/ 2020-11-17 (57)	Lost to Follow-Up
US3452381	2020-09-22	3	No/ 2020-10-22 (31)	Withdrawal of Consent by Participant/ WITHDRAWAL OF CONSENT BY PARTICIPANT,		No/ 2020-10-22 (31)	Withdrawal of Consent by Participant/ WITHDRAWAL OF CONSENT BY PARTICIPANT,

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3462071	2020-08-07	1	No/ 2020-09-02 (27)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DUE TO PERSONAL REASONS.		No/ 2020-09-02 (27)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DUE TO PERSONAL PROBLEMS.
US3462133	2020-08-12	2	No/ 2020-09-03 (23)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT DUE TO UNSTABLE HEALTH.		No/ 2020-09-03 (23)	Withdrawal of Consent by Participant/ PATIENT WITHDREW CONSENT DUE TO UNSTABLE HEALTH.
US3482064	2020-08-17	1	ONGOING			No/ 2020-09-14 (29)	Adverse Event/ AE#1

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3492155	2020-09-15	3	No/ 2020-11-17 (64)	Withdrawal of Consent by Participant/ ADVANCED AGE, DIFFICULTY AMBULATING, DIFFICULTY FINDING PARKING NEAR CLINIC		Yes/ 2020-10-13 (29)	
US3502066	2020-08-31	3	No/ 2020-10-30 (61)	Withdrawal of Consent by Participant/ SHE CANNOT COMMIT BECAUSE SHE HAS TO TAKE CARE OF HER SICK FATHER.		Yes/ 2020-09-29 (30)	

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3502135	2020-09-10	3	No/ 2020-10-29 (50)	Withdrawal of Consent by Participant/ HE LIVES TOO FAR AWAY AND DOES NOT THINK HE COULD COMMIT TO STUDY VISITS, ESPECIALLY SINCE HE DID NOT (AND CANNOT) RECEIVE THE SECOND DOSE.			
US3512042	2020-08-12	2	No/ 2020-09-01 (21)	Death	2020-09-01/ UNK	No/ 2020-09-01 (21)	Death

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3512237	2020-09-05	3	No/ 2020-10-07 (33)	Withdrawal of Consent by Participant/ SUBJECT STATED HE IS NO LONGER INTERESTED IN THE STUDY AND DOES NOT WANT TO RECEIVE THE SECOND DOSE. HE STATES HE DOES NOT WANT TO COMPLETE ANYMORE VISITS OR BE CALLED FOR ANY PHONE VISITS.		No/ 2020-10-07 (33)	Withdrawal of Consent by Participant/ SUBJECT STATED HE IS NO LONGER INTERESTED IN THE STUDY AND DOES NOT WANT TO RECEIVE THE SECOND DOSE. HE STATES HE DOES NOT WANT TO COMPLETE ANYMORE VISITS OR BE CALLED FOR ANY PHONE VISITS.

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3522182	2020-08-18	1	No/ 2020-09-18 (32)	Withdrawal of Consent by Participant/ PARTICIPANT CALLED US ON 18 SEP 2020 ASKING TO WITHDRAW IN PREPARATION FOR AN FDA APPROVED VACCINE		Yes/ 2020-09-11 (25)	
US3522351	2020-08-25	2	No/ 2020-09-11 (18)	Withdrawal of Consent by Participant/ PARTICIPANT MOVED AND WITHDREW AS THEY COULD NOT MAKE THE COMMITMENT.		No/ 2020-09-11 (18)	Withdrawal of Consent by Participant/ PARTICIPANT MOVED AND WITHDREW AS THEY COULD NOT MAKE THE COMMITMENT.

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3522664	2020-09-11	3	ONGOING			No/ 2020-10-12 (32)	Adverse Event/ AE#1
US3522665	2020-09-11	3	ONGOING			No/ 2020-10-17 (37)	Other/ PARTICIPANT DOES NOT CONSENT TO THE SECOND DOSE, BUT DOES TO ALL FUTURE VISITS
US3532279	2020-09-10	3	ONGOING			No/ 2020-10-08 (29)	Adverse Event/ AE #1
US3542332	2020-10-09	4	ONGOING			No/ 2020-11-12 (35)	Serious Adverse Event/ SAEID USA-US084-2020-MRNA-1273-P301000004

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3552024	2020-08-13	2	ONGOING			No/ 2020-09-14 (33)	Other/ SUBJECT CONSENTS FOR FOLLOW-UP, BUT NOT FOR SECOND VACCINATION.
US3552035	2020-08-14	2	ONGOING			No/ 2020-09-17 (35)	Adverse Event/ AE #1
US3552189	2020-08-26	3	ONGOING			No/ 2020-09-07 (13)	Physician Decision/ SUBJECT IS POOR HISTORIAN FOR RECORDING REACTOGENICITY; DOES NOT MAKE OBJECTIVE MEASURES. PI DISCRETION TO NOT VACCINATE.

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3552326	2020-09-04	3	No/ 2020-10-05 (32)	Withdrawal of Consent by Participant/ SUBJECT WOULD LIKE TO WITHDRAW DUE TO CHANGES IN WORK SCHEDULE AND SCHOOL SCHEDULE.		No/ 2020-10-05 (32)	Withdrawal of Consent by Participant/ SUBJECT WOULD LIKE TO WITHDRAW DUE TO CHANGES IN WORK SCHEDULE AND SCHOOL SCHEDULE.
US3552371	2020-09-08	3	ONGOING			No/ 2020-10-13 (36)	Adverse Event/ AE #2
US3552497	2020-09-26	3	ONGOING			No/ 2020-10-29 (34)	Adverse Event/ AE #1

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3552499	2020-09-26	3	ONGOING			No/ 2020-10-29 (34)	Physician Decision/ SUBJECT BEING WORKED UP FOR HEADACHE (PART OF MEDICAL HISTORY)
US3562003	2020-08-04	1	No/ 2020-08-10 (7)	Withdrawal of Consent by Participant/ PT DOES NOT WANT TO CONTINUE WITH STUDY DUE TO PERSONAL REASON AND WITHDREW CONSENT		No/ 2020-08-10 (7)	Withdrawal of Consent by Participant/ DOES NOT WANT TO CONTINUE WITH STUDY DUE TO PERSONAL REASON

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3562011	2020-08-06	1	No/ 2020-11-03 (90)	Withdrawal of Consent by Participant/ PT WAS NOT ABLE TO COMPLIANCE WITH STUDY PROCEDURE AND NEVER RETURN FOR VISIT 3 !		Yes/ 2020-09-03 (29)	
US3562017	2020-08-07	1	No/ 2020-10-02 (57)	Withdrawal of Consent by Participant/ DURING VISIT 3 PATIENT CHANGED HER MIND AND SHE WITHDREW CONSENT !		Yes/ 2020-09-04 (29)	

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

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US3562051	2020-08-17	2	No/ 2020-10-12 (57)	Withdrawal of Consent by Participant/ PT DOES NOT WANT TO CONTINUE WITH STUDY . SHE STATES HER PCP ADVICE HER TO WITHDREW		Yes/ 2020-09-14 (29)	
US3562230	2020-10-15	4	No/ 2020-11-20 (37)	Withdrawal of Consent by Participant/ DOE NOT WANT TO CONTINUE WITH STUDY DUE TO RECENT HOSPITALIZED		No/ 2020-11-20 (37)	Withdrawal of Consent by Participant/ PT DOES NOT WANT TO CONTINUE WITH STUDY AS HE RECENTLY GOT DISCHARGE FROM HOSPITAL

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3592019	2020-08-05	1	No/ 2020-08-05 (1)	Lost to Follow-Up		No/ 2020-09-30 (57)	Lost to Follow-Up
US3592120	2020-08-11	2	ONGOING			No/ 2020-09-08 (29)	Other/ SUBJECT TAKING PROHIBITED MEDICATION
US3622180	2020-09-12	3	No/ 2020-10-27 (46)	Withdrawal of Consent by Participant/ WITHDREW CONSENT		Yes/ 2020-10-13 (32)	

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Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

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US3622217	2020-09-22	3	No/ 2020-10-08 (17)	Withdrawal of Consent by Participant/ PARTICIPANT WITHDREW CONSENT AS SHE HAS "TOO MUCH GOING ON"		No/ 2020-10-08 (17)	Withdrawal of Consent by Participant/ PARTICIPANT WITHDREW CONSENT AS SHE HAS "TOO MUCH GOING ON"
US3632135	2020-10-15	4	No/ 2020-10-20 (6)	Withdrawal of Consent by Participant/ PARTICIPANT ASKED TO WITHDRAW FROM THE STUDY BECAUSE HE FELT OVERWHELMED.		No/ 2020-10-20 (6)	Withdrawal of Consent by Participant/ PARTICIPANT ASKED TO WITHDRAW FROM THE STUDY BECAUSE HE FELT "OVERWHELMED" WITH THE STUDY PROCEDURES.

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3642268	2020-09-21	3	ONGOING			No/ 2020-10-21 (31)	Adverse Event/ NEUROPATHY TEMPORALLY ASSOCIATED WITH VACCINE DOSE 1
US3662029	2020-08-31	3	ONGOING			No/ 2020-10-08 (31)	Other/ DID NOT MEET EXCLUSION CRITERIA 11,
US3672092	2020-08-13	2	ONGOING			No/ 2020-09-09 (28)	Adverse Event/ AE 1 AND AE 2
US3672163	2020-08-18	2	ONGOING			No/ 2020-08-28 (11)	Adverse Event/ RIGHT ARM ERYTHEMA, RIGHT ARM INDURATION

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

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US3672251	2020-08-21	2	ONGOING			No/ 2020-09-23 (34)	Adverse Event/ PARTICIPANT DECLINED DUE TO INJECTION SITE REACTION ON D8, SUBJECT DECLINED SECOND VACCINATION
US3672377	2020-08-28	3	ONGOING			No/ 2020-09-30 (34)	Physician Decision/ PHYSICIAN DECISION WITHDRAWAL OF EXPERIENCES AN AE OR SAW THAT, IN THE JUDGEMENT OF THE INVESTIGATOR, REQUIRES STUDY IP WITHDRAWAL DUE TO IT'S NATURE

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Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3722352	2020-08-24	2	No/ 2020-10-16 (54)	Lost to Follow-Up		No/ 2020-10-16 (54)	Lost to Follow-Up
US3732134	2020-08-21	2	No/ 2020-10-13 (54)	Lost to Follow-Up		No/ 2020-10-13 (54)	Lost to Follow-Up
US3742097	2020-08-26	3	ONGOING			No/ 2020-09-09 (15)	Other/ VOLUNTEER DECLINED 2ND VACCINATION. WILL CONTINUE IN STUDY FOR FOLLOW UP.
US3742169	2020-08-31	3	ONGOING			No/ 2020-10-03 (34)	Serious Adverse Event/ SAE (AE#2)

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
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Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

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US3742368	2020-09-14	3	No/ 2020-10-22 (32)	Withdrawal of Consent by Participant/ HE NO LONGER WANT TO PARTICIPATE BECAUSE HIS FAMILY DOES NOT WANT HIM TO DO.		No/ 2020-10-22 (32)	Withdrawal of Consent by Participant/ PARTICIPANT STATED FAMILY DOESN'T WANT HIM TO PARTICIPATE
US3742397	2020-09-17	3	No/ 2020-10-14 (28)	Withdrawal of Consent by Participant/ PARTICIPANT WANTED CASH NOT GIFT CARD AS PAYMENT.			

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3752173	2020-08-20	2	No/ 2020-11-01 (74)	Death	2020-11-01/ UNK	Yes/ 2020-09-18 (30)	
US3752224	2020-08-24	2	No/ 2020-09-28 (36)	Lost to Follow-Up		No/ 2020-09-22 (30)	Lost to Follow-Up
US3772012	2020-08-05	1	No/ 2020-10-13 (70)	Physician Decision/ NONCOMPLIANCE WITH THE PROTOCOL		Yes/ 2020-09-08 (35)	
US3772013	2020-08-05	1	No/ 2020-10-15 (72)	Physician Decision/ NONCOMPLIANCE WITH THE PROTOCOL.		Yes/ 2020-09-08 (35)	

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Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3772107	2020-08-20	2	No/ 2020-10-20 (62)	Lost to Follow-Up		No/ 2020-10-20 (62)	Lost to Follow-Up
US3782111	2020-08-28	3	ONGOING			No/ 2020-09-25 (29)	Other/ PARTICIPANT AGREES TO BE FOLLOWED BUT DECLINES SECOND VACCINATION OVER CONCERN OF POTENTIAL ADVERSE REACTION
US3812128	2020-08-11	1	No/ 2020-09-01 (22)	Lost to Follow-Up		No/ 2020-08-11 (1)	Lost to Follow-Up
US3822010	2020-08-05	1	No/ 2020-08-27 (23)	Lost to Follow-Up		No/ 2020-08-05 (1)	Lost to Follow-Up

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3832244	2020-08-21	2	No/ 2020-09-25 (36)	Withdrawal of Consent by Participant/ SUBJECT STATED HE IS NOT LONGER ABLE TO PARTICIPATE IN STUDY DUE TO UNEXPECTED INCREASE IN WORKLOAD.			
US3832250	2020-08-24	2	ONGOING			No/ 2020-09-21 (29)	Pregnancy
US3842060	2020-10-21	4	ONGOING			No/ 2020-10-26 (6)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3852056	2020-08-28	3	No/ 2020-10-22 (56)	Withdrawal of Consent by Participant/ SHE HAS CHOSEN TO WITHDRAW FROM THE TRIAL DUE TO THE MIX UP OF DOSES BETWEEN HER AND HER SISTER (2057)		Yes/ 2020-09-25 (29)	
US3852194	2020-09-22	3	No/ 2020-10-21 (30)	Lost to Follow-Up		Yes/ 2020-10-21 (30)	
US3862175	2020-09-11	3	ONGOING			No/ 2020-09-11 (1)	Adverse Event/ AE #1 AND #2
US3862262	2020-09-29	3	ONGOING			No/ 2020-09-29 (1)	Adverse Event/ AE #1

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3862286	2020-10-16	4	ONGOING			No/ 2020-10-16 (1)	Adverse Event/ VIRAL LIKE ILLNESS [UNKNOWN ETIOLOGY]

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3872153	2020-08-12	1	No/ 2020-09-14 (34)	Physician Decision/ SUBJECT WAS NOT COOPERATIVE WHEN TRYING TO RESCHEDULE HIS V2 HE MISSED. SUBJECT SAID HE (b) (6) HE WOULD NOT GIVE FURTHER INFORMATION		No/ 2020-09-14 (34)	Physician Decision/ SUBJECT WAS NOT COOPERATIVE WHEN TRYING TO RESCHEDULE HIS V2 HE MISSED. SUBJECT (b) (6) (b) (6) HE WOULD NOT GIVE FURTHER INFORMATION
US3872318	2020-08-27	2	No/ 2020-09-16 (21)	Death	2020-09-16/ N	No/ 2020-08-27 (1)	Death

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3892001	2020-08-21	2	No/ 2020-09-21 (29)	Lost to Follow-Up		Yes/ 2020-09-21 (29)	
US3902030	2020-09-03	3	ONGOING			No/ 2020-10-01 (29)	Adverse Event/ HIVES
US3922076	2020-09-02	3	No/ 2020-09-14 (13)	Physician Decision/ PI DECISION DUE TO SUBJECT NON-COMPLIANCE		No/ 2020-09-14 (13)	Physician Decision/ PI DECISION DUE TO SUBJECT NON-COMPLIANCE

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3942021	2020-08-28	3	No/ 2020-10-08 (42)	Serious Adverse Event/ PI DISCRETION FOR DUE TO SAFETY FROM SAE#1 AND BEING AN UNDESIRABLE SUBJECT		No/ 2020-10-08 (42)	Serious Adverse Event/ SAE #1-MOTOR VEHICLE ACCIDENT TRAUMA; AE#2-POLY SUBSTANCE ABUSE; PI DISCRETION DUE TO SUBJECT SAFETY AND UNDESIRABLE SUBJECT STATUS
US3942031	2020-08-29	3	No/ 2020-10-23 (56)	Lost to Follow-Up		No/ 2020-10-23 (56)	Lost to Follow-Up

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3942037	2020-09-01	3	No/ 2020-10-13 (43)	Withdrawal of Consent by Participant/ SUBJECT CALLED FOR DAY 36 TC AND YELLED AT SITE THAT THEY NEVER WISHED TO BE CALLED AGAIN AND THEY ARE WITHDRAWING FROM THE STUDY DUE TO PERSONAL REASONS		Yes/ 2020-10-06 (36)	
US3942121	2020-09-17	3	ONGOING			No/ 2020-10-20 (27)	Adverse Event/ AE #10 - COUGH. IP WAS DISCONTINUED DUE TO COVID LIKE SYMPTOMS

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3952032	2020-09-02	2	No/ 2020-10-29 (58)	Withdrawal of Consent by Participant/ MOVING (b) (6)		Yes/ 2020-10-02 (31)	
US3952150	2020-09-24	3	No/ 2020-11-13 (51)	Lost to Follow-Up		No/ 2020-11-13 (51)	Lost to Follow-Up
US3952216	2020-10-09	4	ONGOING			No/ 2020-11-06 (29)	Adverse Event/ HYPERTENSION
US3962094	2020-09-09	3	No/ 2020-10-15 (37)	Death	2020-10-15/ N	No/ 2020-10-15 (37)	Serious Adverse Event/ HEAD TRAUMA
US3982142	2020-09-09	3	No/ 2020-10-13 (35)	Lost to Follow-Up		No/ 2020-09-17 (9)	Lost to Follow-Up

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3982158	2020-09-11	3	No/ 2020-10-16 (36)	Physician Decision/ NON-COMPLIANCE		No/ 2020-09-16 (6)	Physician Decision/ NON-COMPLIANCE

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3042063	2020-08-04	1	ONGOING			No/ 2020-09-01 (29)	Due to SARS-CoV-2
US3042150	2020-08-12	2	ONGOING			No/ 2020-09-09 (29)	Due to SARS-CoV-2
US3162159	2020-08-20	2	ONGOING			No/ 2020-08-26 (7)	Due to SARS-CoV-2
US3172026	2020-08-11	1	ONGOING			No/ 2020-09-08 (29)	Due to SARS-CoV-2
US3172037	2020-08-11	1	No/ 2020-09-15 (36)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW CONSENT DURING THE DAY 29 VISIT.		No/ 2020-09-15 (36)	Withdrawal of Consent by Participant/ SUBJECT REFUSED 2ND DOSE

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172038	2020-08-11	1	ONGOING			No/ 2020-09-04 (25)	Serious Adverse Event/ SAE #2
US3172106	2020-08-14	1	ONGOING			No/ 2020-09-18 (36)	Due to SARS-CoV-2
US3172116	2020-08-14	1	No/ 2020-11-02 (81)	Withdrawal of Consent by Participant		Yes/ 2020-09-11 (29)	
US3172126	2020-08-14	1	ONGOING			No/ 2020-09-11 (29)	Due to SARS-CoV-2
US3172166	2020-08-18	1	ONGOING			No/ 2020-09-15 (29)	Due to SARS-CoV-2
US3172180	2020-08-18	2	ONGOING			No/ 2020-09-15 (29)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172185	2020-08-18	1	ONGOING			No/ 2020-09-14 (28)	Serious Adverse Event/ SAE #1
US3172220	2020-08-19	1	ONGOING			No/ 2020-09-24 (37)	Other/ MISSED VISIT
US3172274	2020-08-21	2	No/ 2020-09-30 (41)	Withdrawal of Consent by Participant/ MOVED TO (b) (6) (b) (6)		No/ 2020-09-30 (41)	Withdrawal of Consent by Participant/ MOVED TO (b) (6) (b) (6)
US3172361	2020-08-27	3	ONGOING			No/ 2020-10-02 (37)	Other/ MISSED VISIT

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3202081	2020-08-08	1	No/ 2020-10-27 (81)	Withdrawal of Consent by Participant/ POSITIVE PCR, PARTICIPANT WITHDRAWAL		No/ 2020-08-15 (8)	Due to SARS-CoV-2
US3212066	2020-08-06	1	ONGOING			No/ 2020-09-11 (37)	Other/ COVID-19 POSITIVE RESULTS
US3302384	2020-08-26	3	ONGOING			No/ 2020-09-02 (8)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3352292	2020-08-25	3	No/ 2020-11-16 (84)	Withdrawal of Consent by Participant/ THE SUBJECT STATED SHE CANNOT CONTINUE PARTICIPATING IN THE STUDY DUE TO THE JOB SCHEDULE. SUBJECT WITHDREW CONSENT		Yes/ 2020-09-19 (26)	
US3362180	2020-08-17	2	No/ 2020-10-26 (71)	Withdrawal of Consent by Participant/ WORK SCHEDULE CONFLICT		No/ 2020-10-26 (71)	Withdrawal of Consent by Participant/ WORK SCHEDULE CONFLICT

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3362183	2020-08-18	2	No/ 2020-09-01 (15)	Withdrawal of Consent by Participant/ WITHDRAWAL OF CONSENT DUE TO BASELINE POSITIVE PCR		No/ 2020-09-01 (15)	Withdrawal of Consent by Participant/ WITHDRAWAL OF CONSENT
US3372092	2020-08-11	1	ONGOING			No/ 2020-09-18 (31)	Due to SARS-CoV-2
US3392008	2020-08-12	2	ONGOING			No/ 2020-08-19 (8)	Due to SARS-CoV-2
US3412087	2020-07-31	1	ONGOING			No/ 2020-08-28 (29)	Due to SARS-CoV-2
US3442204	2020-09-30	3	ONGOING			No/ 2020-10-26 (27)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3452295	2020-08-06	1	ONGOING			No/ 2020-08-10 (5)	Due to SARS-CoV-2
US3452406	2020-09-24	3	ONGOING			No/ 2020-10-21 (27)	Due to SARS-CoV-2
US3472090	2020-10-02	3	ONGOING			No/ 2020-10-06 (5)	Due to SARS-CoV-2
US3492030	2020-08-31	2	ONGOING			No/ 2020-09-04 (5)	Due to SARS-CoV-2
US3492295	2020-10-09	3	ONGOING			No/ 2020-10-15 (7)	Due to SARS-CoV-2
US3512063	2020-08-13	2	ONGOING			No/ 2020-08-13 (1)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3522353	2020-08-25	2	ONGOING			No/ 2020-08-25 (1)	Due to SARS-CoV-2
US3522637	2020-09-09	3	ONGOING			No/ 2020-09-12 (4)	Due to SARS-CoV-2
US3552530	2020-10-14	4	ONGOING			No/ 2020-10-14 (1)	Due to SARS-CoV-2
US3572100	2020-08-26	3	ONGOING			No/ 2020-08-31 (6)	Due to SARS-CoV-2
US3592196	2020-08-16	2	ONGOING			No/ 2020-08-16 (1)	Due to SARS-CoV-2
US3742044	2020-08-22	2	ONGOING			No/ 2020-08-28 (7)	Due to SARS-CoV-2

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3792014	2020-08-12	2	ONGOING			No/ 2020-08-14 (3)	Due to SARS-CoV-2
US3802225	2020-09-11	3	ONGOING			No/ 2020-09-15 (5)	Due to SARS-CoV-2
US3812146	2020-08-12	1	No/ 2020-09-02 (22)	Lost to Follow-Up		No/ 2020-08-12 (1)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3822175	2020-08-18	2	No/ 2020-09-23 (37)	Withdrawal of Consent by Participant/ PER PATIENT, SINCE HE WOULD NOT BE RECEIVING SECOND DOSE OF VACCINE, HE WANTED TO WITHDRAW FROM THE STUDY.		No/ 2020-08-18 (1)	Withdrawal of Consent by Participant/ PER PATIENT, SINCE HE WOULD NOT BE RECEIVING SECOND DOSE OF VACCINE, HE WANTED TO WITHDRAW FROM THE STUDY.
US3852018	2020-08-25	3	ONGOING			No/ 2020-08-25 (1)	Due to SARS-CoV-2
US3872312	2020-08-26	2	ONGOING			No/ 2020-09-23 (29)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3942006	2020-08-24	2	No/ 2020-09-28 (36)	Withdrawal of Consent by Participant/ SUBJECT WITHDREW FROM STUDY WHILE ONSITE.		No/ 2020-09-28 (36)	Withdrawal of Consent by Participant/ SUBJECT REFUSED TO COMPLETE STUDY PROCEDURES AND DECIDED TO WITHDRAW FROM STUDY
US3982212	2020-09-21	3	ONGOING			No/ 2020-09-25 (5)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3002223	2020-09-01	3	ONGOING			No/ 2020-09-08 (8)	Due to SARS-CoV-2
US3012118	2020-08-12	2	ONGOING			No/ 2020-08-17 (6)	Due to SARS-CoV-2
US3012352	2020-10-20	4	ONGOING			No/ 2020-11-17 (29)	Due to SARS-CoV-2
US3022012	2020-07-27	1	ONGOING			No/ 2020-08-02 (7)	Due to SARS-CoV-2
US3062235	2020-08-14	2	ONGOING			No/ 2020-08-14 (1)	Due to SARS-CoV-2
US3092099	2020-08-10	2	ONGOING			No/ 2020-09-09 (31)	Pregnancy

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3152201	2020-08-14	2	No/ 2020-11-12 (91)	Lost to Follow-Up		No/ 2020-11-12 (91)	Lost to Follow-Up
US3172011	2020-08-10	1	ONGOING			No/ 2020-09-08 (30)	Due to SARS-CoV-2
US3172091	2020-08-13	1	ONGOING			No/ 2020-09-10 (29)	Due to SARS-CoV-2
US3172233	2020-08-20	1	ONGOING			No/ 2020-09-25 (37)	Other/ MISSED VISIT
US3172261	2020-08-21	1	ONGOING			No/ 2020-09-26 (37)	Other/ MISSED VISIT
US3172268	2020-08-21	1	ONGOING			No/ 2020-09-22 (33)	Lost to Follow-Up

* indicates re-screen subjects.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3172298	2020-08-24	2	ONGOING			No/ 2020-09-28 (36)	Due to SARS-CoV-2
US3172301	2020-08-24	2	ONGOING			No/ 2020-09-23 (31)	Due to SARS-CoV-2
US3172314	2020-08-25	3	ONGOING			No/ 2020-09-30 (37)	Other/ SUBJECT DID NOT COME TO THE VISIT.
US3172382	2020-10-16	3	ONGOING			No/ 2020-10-20 (5)	Due to SARS-CoV-2
US3192889	2020-10-21	4	ONGOING			No/ 2020-11-18 (29)	Other/ ASYMPTOMATIC POSITIVE PCR SWAB
US3212016	2020-08-03	1	ONGOING			No/ 2020-08-07 (5)	Due to SARS-CoV-2

* indicates re-screen subjects.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3242082	2020-08-13	2	ONGOING			No/ 2020-08-26 (14)	Due to SARS-CoV-2
US3242119	2020-08-17	2	ONGOING			No/ 2020-08-26 (10)	Due to SARS-CoV-2
US3242224	2020-08-26	3	ONGOING			No/ 2020-08-31 (6)	Due to SARS-CoV-2
US3252075	2020-08-07	1	ONGOING			No/ 2020-08-13 (7)	Due to SARS-CoV-2
US3272074	2020-08-07	1	No/ 2020-10-12 (67)	Lost to Follow-Up			
US3292412	2020-09-24	3	No/ 2020-09-25 (2)	Adverse Event/ DUE TO SARS-COVID19		No/ 2020-09-25 (2)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3322048	2020-08-20	2	ONGOING			No/ 2020-08-25 (6)	Due to SARS-CoV-2
US3322364	2020-09-17	3	No/ 2020-10-09 (23)	Withdrawal of Consent by Participant/ PATIENT VERBALLY REQUESTED TO WITHDRAW FROM THE STUDY DURING SAFETY CALL DAY 22		No/ 2020-10-09 (23)	Withdrawal of Consent by Participant/ PATIENT VERBALLY REQUESTED TO WITHDRAW FROM THE STUDY DURING SAFETY CALL DAY 22
US3342198	2020-09-04	3	ONGOING			No/ 2020-09-11 (8)	Due to SARS-CoV-2
US3342326	2020-10-02	3	ONGOING			No/ 2020-10-27 (16)	Due to SARS-CoV-2

* indicates re-screen subjects.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3352055	2020-08-11	2	ONGOING			No/ 2020-09-10 (31)	Due to SARS-CoV-2
US3352443	2020-09-29	3	No/ 2020-11-16 (49)	Withdrawal of Consent by Participant/ THE SUBJECT STATED HE MOVED TO (b) (6) AND WILL NO LONGER BE ABLE TO PARTICIPATE IN THE STUDY.		No/ 2020-11-16 (49)	Withdrawal of Consent by Participant/ THE SUBJECT STATED HE MOVED TO (b) (6) AND WILL NO LONGER BE ABLE TO PARTICIPATE IN THE STUDY.
US3432187	2020-08-18	2	ONGOING			No/ 2020-08-18 (1)	Due to SARS-CoV-2
US3442211	2020-10-05	3	ONGOING			No/ 2020-10-20 (16)	Due to SARS-CoV-2

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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3452200	2020-08-04	1	ONGOING			No/ 2020-09-11 (39)	Due to SARS-CoV-2
US3452401	2020-09-24	3	No/ 2020-11-17 (55)	Lost to Follow-Up		No/ 2020-11-17 (55)	Lost to Follow-Up
US3492237	2020-09-22	3	ONGOING			No/ 2020-09-28 (7)	Due to SARS-CoV-2
US3522157	2020-08-17	1	ONGOING			No/ 2020-08-17 (1)	Due to SARS-CoV-2
US3522426	2020-08-28	3	ONGOING			No/ 2020-08-28 (1)	Due to SARS-CoV-2
US3672261	2020-08-21	2	ONGOING			No/ 2020-09-22 (33)	Other/ CONFIRMED POSITIVE COVID-19

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3712171	2020-09-24	3	ONGOING			No/ 2020-09-30 (6)	Due to SARS-CoV-2
US3712209	2020-10-14	4	ONGOING			No/ 2020-10-19 (5)	Due to SARS-CoV-2
US3732262	2020-09-02	3	ONGOING			No/ 2020-09-06 (5)	Adverse Event/ SYMPTOMATIC COVID-19
US3742401	2020-09-17	3	ONGOING			No/ 2020-10-22 (32)	Other/ PARTICIPANT REFUSED FOR SECOND VACCINATION BUT WILL CONTINUE OTHER STUDY PROCEDURES.
US3802162	2020-09-08	3	ONGOING			No/ 2020-09-12 (5)	Due to SARS-CoV-2

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For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3802254	2020-09-15	3	ONGOING			No/ 2020-09-15 (1)	Due to SARS-CoV-2
US3812267	2020-08-26	2	ONGOING			No/ 2020-08-26 (1)	Due to SARS-CoV-2
US3812293	2020-08-28	2	ONGOING			No/ 2020-08-28 (1)	Due to SARS-CoV-2
US3832216	2020-08-19	2	ONGOING			No/ 2020-08-19 (1)	Due to SARS-CoV-2
US3832225	2020-08-19	2	ONGOING			No/ 2020-09-16 (29)	Due to SARS-CoV-2
US3942051	2020-09-02	3	ONGOING			No/ 2020-09-08 (7)	Due to SARS-CoV-2

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.1.1
Subject Disposition for Subjects Who Discontinued from Participation in the Study or Discontinued from Study Vaccine
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Subject ID	Informed Consent Date	Protocol Version	Completed Study/ Date of Study Discontinuation or Completion (Day)	Reason for Study Discontinuation/ Specified Reason	Date of Death/ Autopsy Performed?	Completed Dosing/ Date of Dosing Discontinuation or Completion (Day)	Primary Reason for Dosing Discontinuation/ Specified Reason
US3942091	2020-09-10	3	ONGOING			No/ 2020-09-17 (7)	Due to SARS-CoV-2
US3972224	2020-10-12	4	ONGOING			No/ 2020-10-16 (5)	Due to SARS-CoV-2
US3982123	2020-09-07	3	No/ 2020-10-09 (33)	Lost to Follow-Up		No/ 2020-09-07 (1)	Lost to Follow-Up
US3982190	2020-09-17	3	No/ 2020-10-16 (28)	Lost to Follow-Up		No/ 2020-10-16 (28)	Lost to Follow-Up

* indicates re-screen subjects.
For subjects who did not receive any injection, day is defined as study day from randomization date; for subjects who received at least one injection, day is defined as study day from first injection date.
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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002254; Age (years): 46; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 (6)/ 2020-09-17 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012025; Age (years): 69; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE	2020-07-29 08:00 (1)/ 2020-08-13 07:00 (16)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-07-29 08:00 (1)/ 2020-08-13 07:00 (16)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012031; Age (years): 21; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-05 (7)/ 2020-08-06 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012047; Age (years): 52; Sex: F; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT ELBOW JOINT PAIN	2020-08-28 (1)/ 2020-09-13 (17)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012051; Age (years): 57; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN IN SEVERAL JOINTS	2020-08-28 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

Note: Footnotes are listed on the last page.
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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012082; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-08 15:00 (2)/ 2020-08-15 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-08-08 15:00 (2)/ 2020-08-15 07:00 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012099; Age (years): 60; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-10 (1)/ 2020-08-20 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012149; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-21 (8)/ 2020-08-22 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012151; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-15 (2)/ 2020-08-23 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING, BILATERAL	2020-09-11 19:30 (1)/ 2020-10-24 (44)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012156; Age (years): 59; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-14 13:00 (1)/ 2020-09-23 08:00 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022005; Age (years): 48; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-01 00:00 (1)/ 2020-09-08 00:00 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022123; Age (years): 41; Sex: M; Race: WHITE							
Infections and infestations/ Mastoiditis/ MASTOIDITIS RIGHT	2020-08-10 (5)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022134; Age (years): 42; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-08-12 (3)/ 2020-08-18 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-12 (3)/ 2020-08-21 (12)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022134; Age (years): 42; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-13 (4)/ 2020-08-17 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022283; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-18 20:30 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032108; Age (years): 29; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-08 (4)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Tension headache/ TENSION HEADACHE	2020-08-08 (4)/ 2020-08-25 (21)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032144; Age (years): 63; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ GENERALIZED HEADACHES	2020-09-13 (3)/ 2020-10-06 (26)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042013; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-12 (16)/ 2020-08-18 (22)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIA	2020-08-12 (16)/ 2020-08-18 (22)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3042028; Age (years): 37; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-02 (7)/ 2020-09-06 (11)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042067; Age (years): 41; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-03 16:00 (1)/ 2020-09-13 07:00 (10)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3042187; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING LEFT SHOULD PAIN	2020-08-20 (8)/ 2020-08-20 (8)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042316; Age (years): 45; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 (2)/ 2020-10-04 (11)	Yes/ No/ Yes	1	No	R/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3052001; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-28 (4)/ 2020-08-28 (4)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3052211; Age (years): 29; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-30 (17)/ 2020-08-31 (18)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3052307; Age (years): 54; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-28 17:40 (1)/ 2020-08-30 21:48 (3)	Yes/ No/ No	2	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-28 18:13 (1)/ 2020-09-02 21:48 (6)	Yes/ No/ No	3	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-28 19:40 (1)/ 2020-08-30 21:47 (3)	Yes/ No/ No	2	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062058; Age (years): 36; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-04 (5)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062112; Age (years): 37; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-07 08:00 (1)/ 2020-08-13 20:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-08 (3)/ 2020-08-13 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3062135; Age (years): 55; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES, GENERALIZED	2020-08-12 (7)/ 2020-08-15 (10)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062274; Age (years): 48; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT THE INJECTION SITE	2020-08-18 (2)/ 2020-08-25 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3062281; Age (years): 88; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES, GENERALIZED	2020-08-21 (4)/ 2020-08-26 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082029; Age (years): 47; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY - CONTRALATERAL TO VACCINATION ARM	2020-08-24 (11)/ 2020-08-31 (18)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082073; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-08-27 (8)/ 2020-08-28 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT PAIN	2020-08-27 (8)/ 2020-08-28 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082091; Age (years): 78; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-28 (5)/ 2020-09-27 (35)	Yes/ No/ Yes	2	No	R/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082124; Age (years): 62; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ SHARP PAIN IN HEAD	2020-10-23 (26)/ 2020-10-26 (29)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082177; Age (years): 78; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ MIGRAINE HEADACHE [WAVES]	2020-09-05 (4)/ 2020-09-05 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3092068; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-10 (3)/ 2020-08-19 (12)	Yes/ No/ Yes	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3092103; Age (years): 30; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-01 (9)/ 2020-10-03 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-01 (9)/ 2020-10-03 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092148; Age (years): 29; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-05 (10)/ 2020-11-09 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3092245; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ BODY/ MUSCLE ACHES	2020-09-03 (8)/ 2020-10-04 (39)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3092290; Age (years): 46; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	2020-09-02 (1)/ 2020-09-10 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092290; Age (years): 46; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-16 (18)/ 2020-10-19 (21)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112051; Age (years): 57; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-07-31 (1)/ 2020-08-15 (16)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-01 (2)/ 2020-08-15 (16)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112195; Age (years): 50; Sex: M; Race: WHITE							
Eye disorders/ Visual acuity reduced/ CHANGE OF VISUAL ACUITY	2020-09-28 (20)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112250; Age (years): 31; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-20 (7)/ 2020-08-21 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-08-20 (7)/ 2020-08-21 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112387; Age (years): 67; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-30 (5)/ 2020-09-05 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112393; Age (years): 57; Sex: F; Race: WHITE							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE	2020-09-28 11:25 (1)/ 2020-09-28 11:30 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112414; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (GENERALIZED)	2020-08-28 (2)/ 2020-09-05 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3122006; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-07-30 (4)/ 2020-08-02 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122031; Age (years): 41; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-27 00:00 (1)/ 2020-08-27 23:59 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122070; Age (years): 75; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN - BILATERAL SHOULDERS	2020-08-27 00:00 (30)/ 2020-09-02 23:59 (37)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3132026; Age (years): 39; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (3)/ 2020-09-18 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152016; Age (years): 68; Sex: M; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHT HEADED	2020-07-29 (2)/ 2020-07-29 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152020; Age (years): 43; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-07-28 18:44 (1)/ 2020-07-29 15:00 (1)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152034; Age (years): 22; Sex: F; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-26 13:00 (1)/ 2020-08-26 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-08-26 13:00 (1)/ 2020-08-27 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-26 13:00 (1)/ 2020-09-03 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 13:00 (1)/ 2020-09-06 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152034; Age (years): 22; Sex: F; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (GENERALIZED)	2020-08-26 13:00 (1)/ 2020-09-07 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES (GENERALIZED)	2020-08-26 13:00 (1)/ 2020-09-09 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAINS (GENERALIZED)	2020-09-02 (8)/ 2020-09-10 (16)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152035; Age (years): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ ENLARGED ANTERIOR CERVICAL CHAIN LYMPHNODES	2020-07-29 19:00 (1)/ 2020-07-30 09:30 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152038; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-07 (13)/ 2020-09-10 (16)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152072; Age (years): 55; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-02 08:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152111; Age (years): 40; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-09 (34)/ 2020-09-09 (34)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152118; Age (years): 24; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEFT ARM SPASM	2020-08-12 (6)/ 2020-08-23 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-14 (8)/ 2020-09-18 (43)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152139; Age (years): 49; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT POSTERIOR CERVICAL LYMPHADENOPATHY	2020-09-22 (8)/ 2020-09-22 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152146; Age (years): 49; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-15 (6)/ 2020-09-28 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152164; Age (years): 40; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT PAIN	2020-08-15 (3)/ Ongoing	Yes/ No/ Yes	2	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152172; Age (years): 62; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ INTERMITTENT ARTHRALGIA	2020-08-15 (3)/ 2020-11-07 (87)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152244; Age (years): 26; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES, GENERALIZED	2020-08-17 (3)/ 2020-09-05 (22)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152264; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-18 (4)/ 2020-09-14 (31)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152283; Age (years): 48; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-08-24 (8)/ 2020-08-27 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-24 (8)/ 2020-08-27 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152308; Age (years): 34; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH	2020-09-26 (6)/ 2020-10-02 (12)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152329; Age (years): 37; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS BACK	2020-09-24 (3)/ 2020-09-26 (5)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152330; Age (years): 29; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-25 (9)/ 2020-09-26 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152362; Age (years): 31; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-26 (3)/ 2020-10-09 (16)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152367; Age (years): 70; Sex: F; Race: ASIAN							
Nervous system disorders/ Dizziness/ INTERMITTENT DIZZINESS	2020-08-24 (4)/ 2020-09-07 (18)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-01 (8)/ 2020-10-06 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-01 (8)/ 2020-10-08 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152367; Age (years): 70; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-01 (8)/ 2020-10-08 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-10-01 (8)/ 2020-10-08 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-01 (8)/ 2020-10-08 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152374; Age (years): 54; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-22 00:00 (1)/ 2020-08-30 00:00 (9)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152374; Age (years): 54; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ ENLARGED SUBMANDIBULAR LYMPH NODES	2020-08-28 (8)/ 2020-09-04 (15)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Pruritus/ ITCHY HANDS	2020-10-28 (34)/ 2020-10-28 (34)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152378; Age (years): 44; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT ANTERIOR CERVICAL CHAIN LYMPH ADENOPATHY	2020-08-29 (8)/ 2020-09-01 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152386; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ WORSENING OF MIGRAINES	2020-08-30 (6)/ 2020-09-02 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152386; Age (years): 49; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-25 00:00 (31)/ 2020-10-05 00:00 (41)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPS	2020-09-26 00:00 (1)/ 2020-10-05 00:00 (10)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Musculoskeletal stiffness/ NECK STIFFNESS	2020-09-30 (6)/ 2020-10-05 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152465; Age (years): 33; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Herpes simplex/ HSV TYPE 1 OUTBREAK ON LIPS	2020-11-14 (3)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152473; Age (years): 56; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIAS	2020-10-20 (8)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3152484; Age (years): 68; Sex: M; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-17 (4)/ 2020-10-21 (8)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152487; Age (years): 18; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-21 (8)/ 2020-10-23 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152487; Age (years): 18; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-24 (11)/ 2020-10-27 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152500; Age (years): 26; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Musculoskeletal stiffness/ NECK STIFFNESS	2020-10-18 (4)/ 2020-11-02 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152539; Age (years): 25; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-29 (8)/ 2020-10-29 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162009; Age (years): 67; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT (CONTRALATERAL)AXILLARY LYMPHADENOPATHY ONGOING AFTER DAY 7	2020-08-28 (4)/ 2020-09-03 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162012; Age (years): 54; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 (2)/ 2020-09-03 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162109; Age (years): 39; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-15 (7)/ 2020-09-19 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162110; Age (years): 69; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-09-11 (2)/ 2020-09-28 (19)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162163; Age (years): 43; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ BILATERAL AXILLARY LYMPHADENOPATHY BEYOND DAY 7	2020-09-08 (20)/ 2020-09-12 (24)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162178; Age (years): 45; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE AFTER DAY 7, MACULAR, NON-URTICARIAL	2020-08-24 17:06 (1)/ 2020-08-31 21:08 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162203; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-01 (5)/ 2020-09-16 (20)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162217; Age (years): 68; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ ACUTE DIARRHEA	2020-10-03 03:00 (1)/ 2020-10-04 07:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162240; Age (years): 23; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE AFTER DAY 7	2020-09-15 19:58 (1)/ 2020-09-23 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172075; Age (years): 49; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-08-17 (6)/ 2020-08-25 (14)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172144; Age (years): 44; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-25 (12)/ 2020-09-29 (16)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172211; Age (years): 53; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIB CAGE ARTHRALGIA (LEFT SIDED)	2020-09-25 (10)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172311; Age (years): 42; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ LEFT DELTOID IMJECTION SITE PAIN	2020-09-01 (8)/ 2020-09-06 (13)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172311; Age (years): 42; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ LEFT DELTOID INJECTION SITE TENDERNESS	2020-09-01 (8)/ 2020-09-06 (13)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-10-01 (8)/ 2020-10-17 (24)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172340; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA GENERALIZED	2020-09-23 (3)/ 2020-09-29 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172340; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA GENERALIZED	2020-09-23 (3)/ 2020-09-29 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-09-24 (4)/ 2020-09-29 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172361; Age (years): 36; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-03 (8)/ 2020-09-03 (8)	Yes/ No/ No	1	No	R/ NR	/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3182242; Age (years): 36; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-08-17 (4)/ 2020-08-22 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192654; Age (years): 38; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN LEFT AXILLARY LYMPH NODE	2020-11-06 (37)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202057; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (UNKNOWN ETIOLOGY)	2020-09-09 (7)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202066; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ SORENESS AT INJECTION SITE	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202092; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ MACULAR, NON URTICARIAL REDNESS MEASURING 3X4MM AT INJECTION SITE	2020-08-18 (10)/ 2020-08-20 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-18 (10)/ 2020-08-20 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-08-18 (10)/ 2020-08-20 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202092; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-08-18 (10)/ 2020-08-20 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212004; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE (REACTOGENICITY)	2020-08-09 (7)/ 2020-08-11 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA (REACTOGENICITY)	2020-08-09 (7)/ 2020-08-11 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212004; Age (years): 38; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA (REACTOGENICITY)	2020-08-09 (7)/ 2020-08-11 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212009; Age (years): 36; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-04 (2)/ 2020-08-11 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212012; Age (years): 40; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-11 (9)/ 2020-08-16 (14)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212063; Age (years): 55; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-06 16:55 (1)/ 2020-08-15 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-06 16:55 (1)/ 2020-08-15 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212077; Age (years): 67; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPADENOPATHY (IPSILATERAL TO INJECTION SITE)	2020-09-03 (29)/ 2020-11-11 (98)	Yes/ No/ No	1	No	R/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212077; Age (years): 67; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT INGUINAL LYMPHADENOPATHY - IPSILATERAL TO INJECTION SITE	2020-09-25 (3)/ 2020-10-11 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212133; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-11 22:24 (1)/ 2020-09-24 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212152; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-12 17:50 (1)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212238; Age (years): 26; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin discolouration/ SKIN DISCOLORATION	2020-10-12 (25)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3212261; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-21 (2)/ 2020-08-29 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY (IPSILATERAL)	2020-08-25 (6)/ 2020-08-28 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212269; Age (years): 32; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE (REACTOGENICITY)	2020-08-20 18:16 (1)/ 2020-08-28 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212276; Age (years): 81; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-08-20 21:45 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3212351; Age (years): 39; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ THROAT IRRITATION	2020-09-05 (3)/ 2020-09-07 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222015; Age (years): 85; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-06 15:33 (1)/ 2020-08-07 16:03 (2)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222031; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION - EXACERBATION	2020-08-07 12:51 (1)/ Ongoing	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222081; Age (years): 59; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT THE INJECTION SITE	2020-09-11 (1)/ 2020-09-20 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222153; Age (years): 84; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-12 00:00 (29)/ 2020-09-20 00:00 (37)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222292; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-25 (3)/ 2020-09-04 (13)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222292; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 (3)/ 2020-10-15 (18)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222538; Age (years): 40; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-10 (7)/ 2020-10-11 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222561; Age (years): 66; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-08 (2)/ 2020-09-24 (18)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222570; Age (years): 62; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPH GLAND SWELLING RIGHT NECK	2020-10-16 (8)/ 2020-10-18 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222574; Age (years): 53; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-09 (1)/ 2020-10-17 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222618; Age (years): 55; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-25 (7)/ 2020-09-27 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-24 00:00 (35)/ 2020-10-28 00:00 (39)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-30 (7)/ 2020-11-01 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222618; Age (years): 55; Sex: M; Race: ASIAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-30 (7)/ 2020-11-04 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222640; Age (years): 64; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ LEFT SIDE PAIN/MUSCLE ACHES	2020-10-26 (3)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222642; Age (years): 22; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-03 (8)/ 2020-10-05 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-03 (8)/ 2020-10-11 (16)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222642; Age (years): 22; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 (8)/ 2020-10-11 (16)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-31 (8)/ 2020-11-16 (24)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-11-01 (9)/ 2020-11-07 (15)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222642; Age (years): 22; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-01 (9)/ 2020-11-11 (19)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE	2020-11-01 (9)/ 2020-11-12 (20)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222646; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-05 (7)/ 2020-10-06 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222657; Age (years): 71; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-06 (6)/ 2020-10-09 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ ACHING PAIN LOWER EXTREMITIES	2020-11-06 (8)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3232068; Age (years): 58; Sex: F; Race: WHITE							
Cardiac disorders/ Palpitations/ WORSENED HEART PALPITATIONS	2020-09-28 (6)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242015; Age (years): 73; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-07 16:50 (1)/ 2020-09-03 (28)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE, RIGHT ARM	2020-08-07 17:22 (1)/ 2020-09-03 (28)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site haematoma/ HEMATOMA AT INJECTION SITE	2020-08-07 17:45 (1)/ 2020-09-03 (28)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242015; Age (years): 73; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-15 (8)/ 2020-10-28 (51)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242034; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-18 (9)/ 2020-09-18 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (9)/ 2020-09-18 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242063; Age (years): 39; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING OR TENDERNESS (RIGHT ARM/NOT VACCINE ARM)	2020-08-19 (8)/ 2020-08-19 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242071; Age (years): 42; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE UNDERARM GLAND SWELLING OR TENDERNESS	2020-08-17 (5)/ 2020-08-23 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242087; Age (years): 63; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-08-15 (2)/ 2020-08-24 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242087; Age (years): 63; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-15 (2)/ 2020-08-24 (11)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-15 (2)/ 2020-08-25 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-15 16:53 (2)/ 2020-08-24 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-14 (1)/ 2020-09-22 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242087; Age (years): 63; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-14 20:00 (1)/ 2020-09-22 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-15 08:00 (1)/ 2020-09-22 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-15 08:00 (1)/ 2020-09-22 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-15 08:00 (1)/ 2020-09-22 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242140; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-25 (8)/ 2020-09-25 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-25 (8)/ 2020-09-26 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242166; Age (years): 29; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-26 (7)/ 2020-08-28 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242188; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-26 (5)/ 2020-09-30 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242241; Age (years): 71; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-02 (8)/ 2020-10-02 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242247; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 21:29 (2)/ 2020-10-10 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-03 21:29 (2)/ 2020-10-10 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242251; Age (years): 22; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-30 (3)/ 2020-09-05 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242309; Age (years): 73; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-08 18:30 (2)/ 2020-10-15 (9)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-10 (4)/ 2020-10-15 (9)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242309; Age (years): 73; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-13 (7)/ 2020-10-15 (9)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242334; Age (years): 23; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-23 (8)/ 2020-09-23 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242350; Age (years): 27; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-26 (9)/ 2020-09-26 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-26 (9)/ 2020-09-26 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242362; Age (years): 74; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN, LEFT ARM	2020-10-26 (7)/ 2020-10-27 (8)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE	2020-10-26 (7)/ 2020-10-27 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242365; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-21 (2)/ 2020-10-28 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242367; Age (years): 72; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-29 (8)/ 2020-09-29 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-29 (8)/ 2020-09-29 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242371; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 (8)/ 2020-09-30 (8)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242374; Age (years): 35; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-20 12:00 (27)/ 2020-10-26 (34)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242385; Age (years): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-01 (7)/ 2020-11-04 (10)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242415; Age (years): 42; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-11-11 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242415; Age (years): 42; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-11 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-11-11 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3262030; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE LEFT ARM	2020-08-28 (1)/ 2020-08-31 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3262239; Age (years): 49; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-26 (2)/ 2020-09-27 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3262239; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-26 (2)/ 2020-09-27 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE OR BODY ACHE	2020-09-26 (2)/ 2020-09-27 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282022; Age (years): 46; Sex: M; Race: ASIAN							
Nervous system disorders/ Headache/ HEADACHE	2020-08-07 20:00 (1)/ 2020-08-17 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-09 (3)/ 2020-08-18 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282022; Age (years): 46; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-08-10 (4)/ 2020-08-18 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-08-11 (5)/ 2020-08-18 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-02 18:00 (1)/ 2020-09-29 (28)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282022; Age (years): 46; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-09-02 18:00 (1)/ 2020-09-29 (28)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-02 18:00 (1)/ 2020-09-29 (28)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-04 (3)/ 2020-09-12 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282022; Age (years): 46; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-07 (6)/ 2020-09-10 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282025; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-08-16 (7)/ 2020-08-18 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES, MULTIPLE SITES	2020-09-05 07:00 (1)/ 2020-09-12 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282025; Age (years): 35; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-05 07:00 (1)/ 2020-09-13 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282029; Age (years): 73; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-08-12 10:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-17 (7)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282072; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 (7)/ 2020-08-28 (8)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282079; Age (years): 52; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSESA	2020-09-25 (5)/ 2020-09-30 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282083; Age (years): 77; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-31 (6)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3282105; Age (years): 76; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 18:00 (1)/ 2020-10-23 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282109; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-27 (7)/ 2020-10-28 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292010; Age (years): 40; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-02 15:00 (2)/ 2020-10-01 (31)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292218; Age (years): 58; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-20 (3)/ 2020-08-20 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292271; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-15 (27)/ 2020-10-16 (28)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292271; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-15 (27)/ 2020-10-21 (33)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-16 (28)/ 2020-10-21 (33)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3302161; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-27 (49)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312004; Age (years): 31; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL UNDERARM TENDERNESS (LYMPHADENOPATHY)	2020-09-16 (10)/ 2020-09-18 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-16 (10)/ 2020-09-18 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312080; Age (years): 63; Sex: F; Race: MULTIPLE: (b) (6)							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-12 (2)/ 2020-09-17 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312086; Age (years): 51; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-15 (2)/ 2020-08-18 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312133; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-23 (6)/ 2020-08-25 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312152; Age (years): 18; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST WALL PAIN (MUSCUOLOSKELETAL)	2020-09-16 13:00 (1)/ 2020-09-25 15:00 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312198; Age (years): 83; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING ON VOLAR SURFACE OF LEFT HAND	2020-09-17 21:00 (1)/ 2020-09-18 10:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312273; Age (years): 25; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT IPSILATERAL AXILLARY LYMPHADENOPATHY	2020-09-22 (1)/ 2020-09-24 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312364; Age (years): 73; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-01 (5)/ 2020-09-02 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312426; Age (years): 42; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-03 (5)/ 2020-10-03 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312475; Age (years): 50; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-04 (2)/ 2020-09-10 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312493; Age (years): 46; Sex: F; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT UNDERARM GLAND SWELLING	2020-09-17 (15)/ 2020-10-08 (36)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312565; Age (years): 79; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ MACULAR NON-URTICARIAL REDNESS AT INJECTION SITE	2020-09-11 (3)/ 2020-09-22 (14)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312627; Age (years): 49; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL (LEFT ARM) UNDERARM SWELLING (LYPMHADENOPATHY)	2020-09-13 (3)/ 2020-09-21 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322036; Age (years): 28; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-25 (2)/ 2020-09-02 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 (6)/ 2020-10-06 (16)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-29 (9)/ 2020-10-06 (16)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322053; Age (years): 49; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-23 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3322056; Age (years): 20; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY (PAIN), IPSILATERAL	2020-09-18 (1)/ 2020-10-02 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3322061; Age (years): 57; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY LYMPHADENOPATHY, LEFT AXILLA	2020-08-27 (7)/ 2020-08-28 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322064; Age (years): 46; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Tinnitus/ TINNITUS	2020-10-03 (11)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322129; Age (years): 43; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-01 (4)/ 2020-09-06 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-03 (6)/ 2020-09-06 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322189; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 08:00 (1)/ 2020-10-08 08:00 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322189; Age (years): 62; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-01 (3)/ 2020-10-02 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-05 (7)/ 2020-10-06 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3322204; Age (years): 37; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ INTERMITTENT FATIGUE	2020-09-06 (4)/ 2020-09-10 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3322259; Age (years): 69; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE SORENESS	2020-10-07 (2)/ 2020-10-14 (9)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322362; Age (years): 42; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 (1)/ 2020-10-12 (26)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322370; Age (years): 48; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-26 (8)/ 2020-10-27 (9)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322400; Age (years): 42; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-30 (24)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-30 (24)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322400; Age (years): 42; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-30 (24)/ 2020-11-01 (26)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-11-01 (26)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Anosmia/ LOSS OF SMELL	2020-11-01 (26)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-01 (26)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322405; Age (years): 27; Sex: M; Race: MULTIPLE:					(b) (6)		
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-08 (7)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3332042; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE - INTERMITTENT	2020-09-16 16:39 (2)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-09-17 (3)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332042; Age (years): 44; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-17 (3)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 (3)/ 2020-09-22 (8)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3332055; Age (years): 19; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-15 (2)/ 2020-09-25 21:13 (12)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332055; Age (years): 19; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	2020-09-16 (3)/ 2020-09-25 (12)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332060; Age (years): 43; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Migraine/ WORSENING OF MIGRIANES	2020-08-25 11:00 (1)/ 2020-08-27 11:00 (3)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332071; Age (years): 51; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Breast pain/ SORE BREASTS BILATERALLY	2020-09-29 08:00 (1)/ 2020-10-01 08:00 (3)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332071; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE- LEFT DELTOID	2020-09-29 21:07 (2)/ 2020-10-11 00:00 (13)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342045; Age (years): 75; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE POST VACCINATION	2020-09-14 15:30 (1)/ 2020-09-30 (17)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342077; Age (years): 34; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY BILATERAL AXILLARY	2020-08-20 18:00 (1)/ 2020-09-03 00:00 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342077; Age (years): 34; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA GENERALIZED	2020-08-26 (7)/ 2020-08-28 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342130; Age (years): 72; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 (8)/ 2020-09-27 (39)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342132; Age (years): 47; Sex: M; Race: WHITE							
Infections and infestations/ Tinea pedis/ TINEA PEDIS (LEFT FOOT)	2020-09-10 (22)/ 2020-10-02 (44)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342182; Age (years): 70; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE POST-VACCINATION	2020-09-03 15:07 (1)/ 2020-09-17 10:00 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342186; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-08 (6)/ 2020-09-11 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342200; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-04 (5)/ 2020-10-16 (17)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-05 (6)/ 2020-10-16 (17)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342201; Age (years): 73; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ ALLERGIC CONTACT DERMATITIS LEFT ARM	2020-09-04 21:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3342227; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-21 (7)/ 2020-10-23 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342229; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Presyncope/ VASOVAGAL REACTION TO SEEING HER OWN BLOOD	2020-09-10 11:40 (1)/ 2020-09-10 11:50 (1)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342229; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING LEFT ARM	2020-09-10 20:30 (1)/ 2020-09-17 14:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342233; Age (years): 29; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ GENERALIZED FATIGUE	2020-10-21 (7)/ 2020-10-23 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342253; Age (years): 24; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pleurisy/ IDIOPATHIC PLEURISY RECURRENCE	2020-09-18 (8)/ 2020-10-19 (39)	Yes/ Yes/ No	2	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342298; Age (years): 42; Sex: M; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenitis/ POST VACCINE LYMPHADENITIS	2020-09-30 12:00 (1)/ 2020-10-02 07:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342362; Age (years): 34; Sex: M; Race: OTHER: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY LYMPHADENOPATHY	2020-10-19 (5)/ 2020-10-24 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-10-20 (6)/ 2020-10-23 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-21 (7)/ 2020-10-23 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352105; Age (years): 28; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (2)/ 2020-10-04 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-05 (5)/ 2020-10-11 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352174; Age (years): 75; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-19 (3)/ 2020-09-22 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352191; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-20 (2)/ 2020-09-28 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352191; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-20 (2)/ 2020-09-28 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352251; Age (years): 69; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (3)/ 2020-10-02 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352373; Age (years): 56; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-14 (5)/ 2020-10-08 (29)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352386; Age (years): 72; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-22 (6)/ 2020-10-25 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352391; Age (years): 45; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-19 19:00 (1)/ 2020-10-03 00:00 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352467; Age (years): 29; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 (1)/ 2020-10-16 (18)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362040; Age (years): 24; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Menstruation irregular/ IRREGULAR MENSTRUATION	2020-08-17 (14)/ 2020-08-22 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362053; Age (years): 51; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ WORSENING OF MIGRAINE/HEADACHE	2020-09-05 00:00 (1)/ 2020-09-19 00:00 (15)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362085; Age (years): 56; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-14 (7)/ 2020-08-14 (7)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362192; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLIN G	2020-09-26 00:00 (1)/ 2020-10-13 00:00 (18)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372005; Age (years): 94; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-08-25 (22)/ 2020-08-25 (22)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372045; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Asthenia/ GENERALIZED ASTHENIA	2020-09-06 (7)/ 2020-09-06 (7)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372079; Age (years): 77; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Asthenia/ GENERALIZED ASTHENIA	2020-09-17 (4)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372103; Age (years): 56; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE-FRONTAL	2020-08-13 (2)/ 2020-08-28 (17)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372113; Age (years): 43; Sex: M; Race: ASIAN							
Nervous system disorders/ Hypogeusia/ SLIGHT DECREASED TASTE	2020-08-24 (12)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372206; Age (years): 27; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY - IPSILATERAL-SAME SIDE OF VACCINATION SITE	2020-09-24 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372206; Age (years): 27; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-24 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3372251; Age (years): 87; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-10-06 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372290; Age (years): 19; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ PYREXIA	2020-10-28 (27)/ 2020-10-30 (29)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372290; Age (years): 19; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-28 (27)/ 2020-10-31 (30)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372322; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-16 (9)/ 2020-10-16 (9)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ PYREXIA	2020-10-16 (9)/ 2020-10-16 (9)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372322; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ MODERATE FATIGUE	2020-10-16 (9)/ 2020-10-17 (10)	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-16 (9)/ 2020-10-17 (10)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-16 (9)/ 2020-10-17 (10)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372322; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-10-16 (9)/ 2020-10-17 (10)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-16 (9)/ 2020-10-25 (18)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372363; Age (years): 53; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-13 (2)/ 2020-10-25 (14)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Haematospermia/ HEMATOSPERMIA	2020-10-13 (2)/ 2020-10-31 (20)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372363; Age (years): 53; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Pyrexia/ PYREXIA	2020-10-20 (9)/ 2020-10-22 (11)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-20 (9)/ 2020-10-23 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372375; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-11-01 (20)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3372375; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-11-01 (20)/ Ongoing	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-11-01 (20)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-01 (20)/ 2020-11-08 (27)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3372375; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-11-03 (22)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-03 (22)/ Ongoing	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-03 (22)/ 2020-11-04 (23)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-04 (23)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372375; Age (years): 70; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-05 (24)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-06 (25)/ Ongoing	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-07 (26)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372375; Age (years): 70; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-11-09 (28)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372400; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	2020-10-19 (4)/ 2020-10-19 (4)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372456; Age (years): 26; Sex: F; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Muscle twitching/ MUSCLE TWITCHES	2020-10-29 (1)/ 2020-10-30 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372469; Age (years): 53; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Dysphagia/ DIFFICULTY SWALLOWING	2020-10-16 12:00 (1)/ 2020-10-16 15:30 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372469; Age (years): 53; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-16 13:00 (1)/ 2020-10-16 18:25 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Parosmia/ PHANTOSMIA	2020-10-20 (5)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382016; Age (years): 38; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-24 (14)/ 2020-08-26 (16)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT ANTERIOR CERVICAL LYMPHADENOPATHY	2020-08-24 (14)/ 2020-09-01 (22)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382042; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-08-28 (12)/ 2020-08-30 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site induration/ INDURATION AT INJECTION SITE	2020-08-28 (12)/ 2020-08-30 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN LYMPH NODES (AXILLARY)	2020-09-02 (17)/ 2020-09-04 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382060; Age (years): 65; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-25 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382155; Age (years): 41; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 (8)/ 2020-10-09 (12)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382241; Age (years): 35; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ CERVICAL LYMPHADENOPATHY-BILATERAL	2020-09-12 (3)/ 2020-09-14 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402296; Age (years): 38; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-11 (4)/ 2020-08-16 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402299; Age (years): 50; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ SEVERE HEADACHE	2020-08-11 (4)/ 2020-08-16 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402332; Age (years): 39; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-13 (2)/ 2020-08-22 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3402430; Age (years): 57; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-14 (24)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3412001; Age (years): 65; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-07-28 (1)/ 2020-07-30 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412008; Age (years): 69; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gingival pain/ GINGIVA SENSITIVITY	2020-07-31 (3)/ 2020-08-01 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-07-31 (3)/ 2020-08-01 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3412156; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ PRURITIS AT INJECTION SITE	2020-08-06 (1)/ 2020-08-07 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3412234; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Gingivitis/ GINGIVITIS	2020-08-23 (11)/ 2020-09-07 (26)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422009; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-09 (30)/ 2020-10-12 (33)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422028; Age (years): 40; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Vaccination complication/ ORAL NONURTICARIAL VESICULAR RASH 6 DAYS FOLLOWING 2ND VACCINATION	2020-09-20 (7)/ 2020-09-27 (14)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422062; Age (years): 40; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site macule/ BENIGN LESION DEVELOPED TO LEFT ARM 8 DAYS AFTER INJECTION AT INJECTION SITE. RAISED RED AREA, SOFT TO TOUCH.	2020-08-27 (8)/ 2020-09-15 (27)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422136; Age (years): 79; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIQUE	2020-09-24 (1)/ 2020-10-08 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (1)/ 2020-10-08 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422154; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES, GENERALIZED	2020-09-29 21:30 (1)/ 2020-10-09 15:00 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE PAIN	2020-09-29 21:30 (1)/ 2020-10-09 15:00 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-04 (6)/ 2020-10-07 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422220; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site erythema/ NON-URTICARIAL REDNESS (17MM) AT R DELTOID INJECTION SITE	2020-09-09 17:00 (2)/ 2020-09-22 08:00 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422310; Age (years): 62; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-01 (4)/ 2020-10-10 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIAS	2020-10-01 (4)/ 2020-10-12 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432008; Age (years): 73; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-03 19:24 (1)/ 2020-09-19 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432020; Age (years): 37; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-09 (3)/ 2020-08-09 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432023; Age (years): 83; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Polymyalgia rheumatica/ POSSIBLE POLYMYALGIA RHEUMATICA	2020-08-20 (16)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-21)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432067; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INJECTION SITE INDURATION	2020-09-08 20:00 (1)/ 2020-09-13 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432068; Age (years): 60; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-12 (3)/ 2020-08-24 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-15 (6)/ 2020-08-19 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432085; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Malaise/ MALAISE	2020-09-16 (3)/ 2020-09-16 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432095; Age (years): 28; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN LYMPH NODE (TONSILLAR)	2020-10-04 (21)/ 2020-10-10 (27)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432108; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-21 (13)/ 2020-09-22 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432120; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Disturbance in attention/ LACK OF CONCENTRATION	2020-08-13 (2)/ 2020-08-14 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432120; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Disturbance in attention/ LACK OF CONCENTRATION	2020-09-08 12:05 (1)/ 2020-09-09 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432127; Age (years): 34; Sex: M; Race: WHITE							
Vascular disorders/ Flushing/ FLUSHING (FACIAL)	2020-09-15 17:30 (1)/ 2020-09-15 21:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432133; Age (years): 59; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-08-15 (3)/ 2020-09-16 (35)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432178; Age (years): 71; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal stiffness/ NECK STIFFNESS	2020-08-19 (2)/ 2020-08-21 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432232; Age (years): 26; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-18 (11)/ 2020-10-20 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432233; Age (years): 23; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-22 (2)/ 2020-08-27 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432248; Age (years): 36; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE (REACTOGENICITY)	2020-08-22 (1)/ 2020-08-23 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432248; Age (years): 36; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE (EXTENDED REACTOGENICITY)	2020-09-19 13:11 (1)/ 2020-10-03 08:00 (14)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432256; Age (years): 42; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-25 (2)/ 2020-09-03 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432260; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Reactogenicity event/ REACTOGENICITY SYNDROME (INTERMITTENT NAUSEA AND HEADACHE)	2020-08-26 (3)/ 2020-09-05 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432330; Age (years): 41; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-31 (4)/ 2020-09-04 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432335; Age (years): 31; Sex: F; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 (5)/ 2020-10-06 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432379; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-18 (6)/ 2020-10-19 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432403; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Reactogenicity event/ REACTOGENICITY	2020-09-09 (8)/ 2020-09-10 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432407; Age (years): 33; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 (8)/ 2020-09-10 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432424; Age (years): 40; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Feeling abnormal/ BRAIN FOG	2020-10-05 (4)/ 2020-10-08 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432431; Age (years): 60; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-08 (5)/ 2020-09-08 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432452; Age (years): 66; Sex: M; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS (GENERALIZED)	2020-09-06 (2)/ 2020-09-14 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432464; Age (years): 72; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-07 (2)/ 2020-10-07 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432502; Age (years): 78; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-25 (13)/ 2020-10-25 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432517; Age (years): 55; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-10-15 13:00 (1)/ 2020-10-15 19:00 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIAS	2020-10-22 (8)/ 2020-10-23 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432527; Age (years): 46; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-19 (2)/ 2020-10-02 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432578; Age (years): 29; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-04 (5)/ 2020-10-05 (6)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432591; Age (years): 58; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-03 (2)/ 2020-11-09 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432630; Age (years): 56; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-27 (7)/ 2020-10-31 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442005; Age (years): 63; Sex: M; Race: WHITE							
Investigations/ Hepatic enzyme increased/ ELEVATED LIVER ENZYMES	2020-09-18 (9)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3442011; Age (years): 52; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-20 (8)/ 2020-08-23 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-20 (8)/ 2020-08-26 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-08-20 (8)/ 2020-08-26 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442011; Age (years): 52; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-08-20 (8)/ 2020-08-29 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442042; Age (years): 80; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 (8)/ 2020-08-29 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-23 (9)/ 2020-09-24 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442042; Age (years): 80; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-23 (9)/ 2020-09-26 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442044; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-23 (4)/ 2020-08-28 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE: BILATERALLY IN SHOULDERS AND LOWER BACK	2020-08-23 (4)/ 2020-09-03 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442044; Age (years): 60; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-08-24 (5)/ 2020-08-28 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442051; Age (years): 42; Sex: M; Race: WHITE							
Eye disorders/ Periorbital pain/ LEFT PERIORBITAL SORENESS	2020-09-22 (6)/ 2020-09-24 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3442056; Age (years): 63; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ BRUISING LEFT BICEP	2020-08-25 (5)/ 2020-09-25 (36)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442080; Age (years): 71; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-28 (6)/ 2020-10-09 (17)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442092; Age (years): 48; Sex: F; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-30 (8)/ 2020-10-01 (9)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442217; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest discomfort/ CHEST DISCOMFORT (GENERAL PAIN)	2020-10-11 (6)/ 2020-10-13 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3452047; Age (years): 26; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-06 (7)/ 2020-08-07 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3452057; Age (years): 26; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-01 (5)/ 2020-09-04 (8)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452099; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-05 (5)/ 2020-08-12 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3452100; Age (years): 42; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-19 (19)/ 2020-08-24 (24)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452136; Age (years): 50; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-09 (7)/ 2020-08-14 (12)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3452173; Age (years): 54; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-09 (6)/ 2020-08-11 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452266; Age (years): 53; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-10 (5)/ 2020-08-13 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462084; Age (years): 40; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-08 (2)/ 2020-08-15 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-08 (2)/ 2020-08-15 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-08-08 (2)/ 2020-08-15 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462084; Age (years): 40; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-08-10 (4)/ 2020-08-15 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462151; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-18 (7)/ 2020-08-21 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462207; Age (years): 42; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 00:00 (30)/ 2020-09-24 00:00 (38)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-16 00:00 (30)/ 2020-09-24 00:00 (38)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462287; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 (6)/ 2020-10-02 (8)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462305; Age (years): 50; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE(POST-DOSE)	2020-08-24 16:33 (1)/ 2020-09-01 13:00 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRYALGIA IN BOTH LEGS (POST-DOSE)	2020-08-24 16:33 (1)/ 2020-09-01 13:00 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462306; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE PAST DAY 7	2020-08-24 16:00 (1)/ 2020-09-01 08:00 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472003; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-02 (3)/ 2020-09-06 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472015; Age (years): 61; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ BILATERAL AXILLARY LYMPHADENOPATHY	2020-10-03 (5)/ 2020-10-06 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472020; Age (years): 55; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-15 (8)/ 2020-09-16 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472022; Age (years): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ NOCTURNAL HYPERHIDROSIS	2020-09-09 18:00 (2)/ 2020-09-12 00:00 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY - GROIN	2020-09-10 (3)/ 2020-09-23 (16)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472055; Age (years): 33; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-21 (6)/ 2020-10-28 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472060; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-19 10:00 (1)/ 2020-09-19 10:01 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472087; Age (years): 26; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-01 07:00 (1)/ 2020-10-02 22:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-29 08:00 (1)/ 2020-10-31 23:59 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472092; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Dyspepsia/ HEARTBURN	2020-11-06 (5)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472092; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-06 (5)/ 2020-11-09 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-11-06 (5)/ 2020-11-09 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-11-06 (5)/ 2020-11-09 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-07 (6)/ 2020-11-09 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472119; Age (years): 25; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-19 21:15 (1)/ 2020-10-26 12:50 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-25 (7)/ 2020-10-26 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-25 (7)/ 2020-10-27 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-16 18:30 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482002; Age (years): 59; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL KNEE PAIN	2020-09-07 (4)/ 2020-09-13 (10)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482060; Age (years): 71; Sex: M; Race: WHITE							
Nervous system disorders/ Dysaesthesia/ DYSESTHESIA IN UPPER BODY	2020-09-12 09:00 (1)/ 2020-09-14 21:00 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-09-15 (5)/ 2020-09-15 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482063; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT ANTERIOR CERVICAL LYMPHADENOPATHY IPSILATERAL TO VACCINATION SITE	2020-09-15 18:00 (2)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482086; Age (years): 74; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-20 (2)/ 2020-08-21 11:59 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 12:08 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482251; Age (years): 82; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-10-14 (7)/ 2020-10-19 (12)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482267; Age (years): 78; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ BRUISED ARM AFTER INJECTION	2020-09-10 10:29 (1)/ 2020-09-10 23:59 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482310; Age (years): 39; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site erythema/ REDNESS ON LEFT ARM, NEAR INJECTION SITE	2020-11-19 (3)/ 2020-11-20 (4)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492001; Age (years): 68; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-08-30 (7)/ 2020-09-30 (38)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492020; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-26 (2)/ 2020-10-01 (7)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492033; Age (years): 61; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ WORSENING OF COPD	2020-09-01 12:00 (1)/ 2020-09-03 12:00 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492033; Age (years): 61; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-02 (4)/ 2020-10-04 (6)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492045; Age (years): 47; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE SORENESS	2020-10-01 12:00 (30)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3492064; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-04 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492064; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-05 (2)/ 2020-09-23 (20)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492068; Age (years): 50; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-02 (29)/ 2020-10-02 (29)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492088; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-06 17:00 (1)/ 2020-10-07 08:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492239; Age (years): 49; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE	2020-10-30 (10)/ 2020-11-02 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492240; Age (years): 27; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-28 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING	2020-11-04 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492244; Age (years): 63; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Back pain/ BODY ACHES TO THE LOWER BACK	2020-10-14 (22)/ 2020-10-19 (27)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502064; Age (years): 51; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ L ARM LYMPHADENOPATHY	2020-10-12 (15)/ 2020-10-22 (25)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502097; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-05 09:00 (1)/ 2020-09-13 12:00 (10)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502097; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-09-05 09:00 (1)/ 2020-09-13 12:00 (10)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-05 09:00 (1)/ 2020-09-17 12:00 (14)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-05 09:00 (1)/ 2020-09-17 12:00 (14)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-05 09:00 (1)/ 2020-09-17 12:00 (14)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502097; Age (years): 61; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA - INTERMITTENT	2020-09-05 09:00 (1)/ 2020-09-22 12:00 (19)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-05 09:00 (1)/ 2020-09-22 12:00 (19)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512003; Age (years): 59; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-09-03 22:30 (2)/ 2020-09-04 07:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512009; Age (years): 78; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Lip swelling/ ALLERGIC REACTION OF INTERMITTENT LIP SWELLING	2020-09-17 (2)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512017; Age (years): 46; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL JOINT ACHES IN KNEE	2020-08-08 (3)/ 2020-08-16 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512040; Age (years): 59; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-18 (7)/ 2020-08-20 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512049; Age (years): 64; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL INJECTION SITE AXILLARY LYMPHADENOPATHY	2020-08-14 (3)/ 2020-08-21 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512049; Age (years): 64; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL INJECTION SITE AXILLARY LYMPHADENOPATHY	2020-09-10 07:00 (1)/ 2020-09-19 12:00 (10)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512055; Age (years): 59; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-11 07:00 (1)/ 2020-09-18 03:00 (8)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Rhinitis/ RHINITIS	2020-09-15 (6)/ 2020-09-15 (6)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-21 (12)/ 2020-09-22 (13)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512055; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-21 (12)/ 2020-09-22 (13)	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-21 (12)/ 2020-09-22 (13)	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIAS GENERALIZED	2020-09-29 (20)/ 2020-09-30 (21)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512055; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-11 (32)/ 2020-10-11 (32)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-15 (36)/ Ongoing	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 (36)/ Ongoing	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512055; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-15 (36)/ Ongoing	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 (36)/ 2020-10-15 (36)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512065; Age (years): 63; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis bullous/ BULLOUS RASH IN RIGHT AXILLARY REGION IPSILATERAL TO INJECTION SITE NON-URTICARIAL	2020-08-14 12:00 (1)/ 2020-08-15 08:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512092; Age (years): 64; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-12 07:00 (1)/ 2020-09-22 07:00 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512115; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 (7)/ 2020-08-28 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512137; Age (years): 56; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-27 (3)/ 2020-09-28 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512160; Age (years): 46; Sex: M; Race: WHITE							
Nervous system disorders/ Sciatica/ LEFT SCIATICA	2020-09-08 (14)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512172; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 20:00 (1)/ 2020-10-02 06:00 (8)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-30 10:00 (2)/ Ongoing	Yes/ No/ Yes	3	No	R/ R	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ELBOWS AND RIGHT HIP JOINT ACHES	2020-08-30 10:00 (2)/ 2020-09-07 10:00 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ SHOULDERS AND RIGHT HIP MUSCLE ACHES	2020-08-30 10:00 (2)/ 2020-09-09 10:00 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES ON FACE AND NECK	2020-08-31 (3)/ Ongoing	Yes/ No/ No	1	No	R/ R	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-31 (3)/ 2020-09-20 (23)	Yes/ No/ Yes	3	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES (FACE AND NECK)	2020-08-31 (3)/ 2020-10-04 (37)	Yes/ No/ No	1	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ INTERMITTENT FATIGUE	2020-09-19 (22)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHES	2020-09-23 (26)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES (FACE AND NECK)	2020-10-08 (41)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512178; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ LEFT DELTOID INJECTION SITE ERYTHEMATOUS PATCH; NON-URTICARIAL	2020-08-30 12:00 (2)/ 2020-09-11 12:00 (14)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ LEFT DELTOID INJECTION SITE ERYTHEMATOUS PATCH; NON-URTICARIAL	2020-09-26 08:00 (1)/ 2020-10-03 18:00 (9)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512185; Age (years): 71; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Injection site pruritus/ INTERMITTENT INJECTION SITE ITCHINESS	2020-09-09 (12)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512197; Age (years): 58; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 (8)/ 2020-09-11 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512252; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site papule/ LEFT DELTOID INJECTION SITE PAPULAR ERYTHEMA	2020-09-11 11:10 (1)/ 2020-09-20 09:00 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ LEFT DELTOID INJECTION SITE ITCHINESS	2020-09-11 11:10 (1)/ 2020-09-20 09:00 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512252; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Instillation site vesicles/ LEFT DELTOID INJECTION SITE BLISTER	2020-09-11 11:10 (1)/ 2020-09-20 09:00 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512256; Age (years): 68; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (7)/ 2020-09-20 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512258; Age (years): 67; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INTERMITTENT INJECTION SITE PAIN	2020-09-20 (9)/ 2020-09-20 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512258; Age (years): 67; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ 100.7 FEVER	2020-10-13 (5)/ 2020-10-14 (6)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512285; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ SHOULDER MUSCLE ACHES	2020-10-04 (5)/ 2020-10-18 (19)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ SHOULDER JOINT ACHES	2020-10-05 (6)/ 2020-10-18 (19)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 (6)/ 2020-10-18 (19)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512285; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-06 (7)/ 2020-10-18 (19)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522040; Age (years): 34; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-19 (13)/ 2020-08-20 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-19 (13)/ 2020-08-21 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522089; Age (years): 27; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE LASTED A DAY.	2020-08-13 09:00 (1)/ 2020-08-14 12:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522128; Age (years): 70; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-08-14 20:47 (1)/ 2020-08-15 23:59 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522163; Age (years): 54; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (4)/ 2020-09-24 (11)	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522240; Age (years): 54; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-14 11:00 (26)/ 2020-09-25 21:00 (37)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522240; Age (years): 54; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-09-14 11:00 (26)/ 2020-09-25 21:00 (37)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-14 11:00 (26)/ 2020-09-25 21:00 (37)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522405; Age (years): 62; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 17:31 (1)/ 2020-09-15 (20)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522408; Age (years): 67; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM SORENESS THAT STARTED AFTER THE DOSE 2 INJECTION. PARTICIPANT DENIES FEVER OR TAKING MEDICATIONS. PER PARTICIPANT LASTED <24HRS	2020-09-26 10:00 (2)/ 2020-09-26 21:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522460; Age (years): 43; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-31 17:00 (1)/ 2020-09-15 09:00 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522460; Age (years): 43; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-06 08:00 (1)/ 2020-10-12 20:00 (8)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522467; Age (years): 62; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES ON FACE/NECK	2020-09-18 (19)/ Ongoing	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AROUND HEAD/NECK/BACK OF ARM INJECTION SITE	2020-10-02 22:00 (1)/ 2020-10-05 08:00 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522477; Age (years): 38; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES (WRISTS AND ANKLES)	2020-09-30 (3)/ 2020-10-14 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-01 (4)/ 2020-10-06 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522500; Age (years): 34; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-09-02 (2)/ 2020-09-02 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522526; Age (years): 23; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-05 (4)/ 2020-10-14 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE	2020-10-05 (4)/ 2020-10-14 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT THE INJECTION SITE	2020-10-05 (4)/ 2020-10-14 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522526; Age (years): 23; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-10-05 (4)/ 2020-10-14 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-05 (4)/ 2020-10-14 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522527; Age (years): 30; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHINESS AT INJECTION SITE	2020-09-04 (3)/ 2020-09-08 (7)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522553; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDDNESS AT INJECTION SITE (LEFT DELTOID) POST 7 DAYS AFTER 1ST INJECTION, LEFT DELTOID	2020-09-03 20:00 (1)/ 2020-09-30 12:00 (27)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE POST 7 DAYS AFTER 2ND INJECTION	2020-10-05 09:00 (32)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522553; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS-1MM ON 30 OCT 2020.	2020-10-05 12:25 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Diarrhoea/ ONE EPISODE OF DIARRHEA	2020-10-06 14:00 (2)/ 2020-10-06 14:05 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532020; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ulnar nerve injury/ ULNAR NERVE IRRITATION	2020-08-16 (4)/ 2020-10-15 (64)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532024; Age (years): 61; Sex: M; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-08-14 (2)/ 2020-08-15 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532033; Age (years): 60; Sex: M; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-16 00:00 (33)/ 2020-10-01 00:00 (48)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532053; Age (years): 37; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Ear pain/ EAR ACHE, LEFT SIDE	2020-08-19 (2)/ 2020-08-19 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532070; Age (years): 79; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ TENDER INDURATION AT INJECTION SITE	2020-10-04 (18)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532074; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site nodule/ L UPPER ARM MUSCLE NODULE (KNOT) NEAR INJECTION SITE	2020-09-22 00:00 (1)/ 2020-09-24 00:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532080; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Axillary pain/ RIGHT AXILLARY PAIN, INTERMITTENT	2020-09-27 (7)/ 2020-09-29 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532134; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE IN MOUTH	2020-08-25 12:00 (1)/ 2020-08-25 13:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532134; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE IN MOUTH	2020-09-23 10:00 (1)/ 2020-09-30 11:00 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532210; Age (years): 58; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN GLAND BEHIND L EAR, LYMPHADENOPATHY	2020-09-08 (8)/ 2020-09-09 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ ARM PAIN ON L SIDE	2020-09-16 (16)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3532226; Age (years): 40; Sex: M; Race: WHITE							
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-09-03 02:00 (1)/ 2020-09-04 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532258; Age (years): 46; Sex: M; Race: WHITE							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE IN MOUTH	2020-09-09 08:48 (1)/ 2020-09-09 08:50 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532265; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ INTERMITTENT ARM PAIN, LEFT ARM	2020-09-17 (9)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3532272; Age (years): 33; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-10-11 (5)/ 2020-10-12 (6)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532273; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	2020-09-16 (8)/ 2020-09-23 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532275; Age (years): 71; Sex: F; Race: MULTIPLE:				(b) (6)			
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-09-14 (5)/ 2020-09-17 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Malaise/ MALAISE	2020-09-15 (6)/ 2020-10-10 (31)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542006; Age (years): 47; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDER PAIN	2020-09-11 (2)/ 2020-09-11 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542019; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ PRURITIS AT INJECTION SITE	2020-08-18 16:45 (1)/ 2020-08-18 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542024; Age (years): 78; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-20 (2)/ 2020-08-20 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED ARTHRALGIAS	2020-08-20 (2)/ 2020-08-20 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542024; Age (years): 78; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-08-20 (2)/ 2020-08-20 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542057; Age (years): 74; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-10 (11)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542061; Age (years): 69; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-08-26 10:23 (1)/ 2020-08-26 10:38 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-09 (15)/ 2020-09-16 (22)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542061; Age (years): 69; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES, GENERALIZED	2020-09-09 (15)/ 2020-09-19 (25)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542098; Age (years): 54; Sex: F; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIA DUE TO EXERCISE	2020-09-02 (6)/ 2020-09-02 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542112; Age (years): 30; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-31 (1)/ 2020-09-02 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542112; Age (years): 30; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-01 (2)/ 2020-09-02 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542156; Age (years): 36; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ PRURITUS AT INJECTION SITE	2020-10-06 10:32 (1)/ 2020-10-06 17:00 (1)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542172; Age (years): 29; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-15 (8)/ 2020-09-15 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542290; Age (years): 61; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED ARTHRALGIAS	2020-10-23 (1)/ 2020-10-31 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542290; Age (years): 61; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIAS	2020-10-23 (1)/ 2020-10-31 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542320; Age (years): 43; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-06 17:30 (1)/ 2020-10-07 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542360; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITUS	2020-10-25 (3)/ 2020-10-26 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552002; Age (years): 40; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Paranasal sinus discomfort/ SINUS PRESSURE	2020-09-13 (7)/ 2020-09-14 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552009; Age (years): 41; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-12 22:09 (1)/ 2020-08-20 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552049; Age (years): 66; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Paraesthesia oral/ TINGLING OF THE TONGUE	2020-08-17 12:00 (1)/ 2020-08-17 12:01 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dysgeusia/ METALLIC TASTE	2020-08-17 12:00 (1)/ 2020-08-17 12:01 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552087; Age (years): 65; Sex: M; Race: WHITE							
Cardiac disorders/ Palpitations/ INCREASED HEART PALPITATIONS	2020-09-12 (25)/ 2020-10-16 (59)	Yes/ Yes/ No	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552111; Age (years): 66; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-23 (4)/ 2020-08-28 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552123; Age (years): 21; Sex: M; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT SIDE NECK LYMPH NODE ENGLARGEMENT	2020-09-24 (7)/ 2020-09-29 (12)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552135; Age (years): 42; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDER PAIN	2020-10-10 (24)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552146; Age (years): 44; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-11 (19)/ 2020-09-11 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552150; Age (years): 53; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-28 (5)/ 2020-08-28 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552151; Age (years): 71; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE JOINT PAIN	2020-08-28 (5)/ 2020-09-15 (23)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE JOINT PAIN	2020-09-26 (6)/ 2020-10-01 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552162; Age (years): 37; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-31 (7)/ 2020-09-02 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-31 (7)/ 2020-09-02 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-01 (8)/ 2020-09-07 (14)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552163; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM SORENESS	2020-10-17 (26)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552218; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 (22)/ 2020-10-19 (25)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-16 (22)/ 2020-10-19 (25)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE							
Cardiac disorders/ Acute myocardial infarction/ NON-ST ELEVATED MYOCARDIAL INFARCTION	2020-09-26 (29)/ 2020-09-26 (29)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hypomagnesaemia/ HYPOMAGNESIA	2020-09-26 (29)/ 2020-10-08 (41)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE							
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-09-26 (29)/ 2020-10-08 (41)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Atrial fibrillation/ PAROXYSMAL ATRIAL FIBRILLATION	2020-09-26 (29)/ 2020-10-30 (63)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: 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.

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Organising pneumonia/ CRYPTOGENIC ORGANIZING PNEUMONIA	2020-09-26 (29)/ 2020-11-19 (83)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-27 (30)/ 2020-09-27 (30)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE	2020-09-28 (31)/ 2020-11-19 (83)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552233; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ UNEXPLAINED RIGHT KNEE PAIN	2020-08-31 (3)/ 2020-09-01 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552235; Age (years): 53; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT ELBOW PAIN	2020-09-25 (3)/ 2020-10-12 (20)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552341; Age (years): 34; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-07 (3)/ 2020-09-14 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552399; Age (years): 58; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS	2020-10-08 18:00 (1)/ 2020-11-09 (33)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3552408; Age (years): 46; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal discomfort/ UPSET STOMACH	2020-09-15 (5)/ 2020-09-15 (5)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552444; Age (years): 74; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ WORSENING ATRIAL FIBRILLATION ARRHYTHMIA	2020-10-01 (16)/ 2020-10-16 (31)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552461; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Taste disorder/ LOST TASTE FOR ALCOHOL	2020-09-17 15:54 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552461; Age (years): 65; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES OF NECK, SHOULDER, AND BACK	2020-09-26 (10)/ 2020-10-11 (25)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552462; Age (years): 52; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 (3)/ 2020-11-03 (21)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552468; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-22 (7)/ 2020-10-29 (14)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552514; Age (years): 19; Sex: F; Race: UNKNOWN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-13 (8)/ 2020-10-28 (23)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Dysmenorrhoea/ WORSENING MENSTRUAL CRAMPS	2020-10-22 (17)/ 2020-10-22 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552530; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED URTICARIAL RASH	2020-10-18 (5)/ 2020-11-13 (31)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562097; Age (years): 30; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ RASH UNDER INJECTION SITE	2020-10-02 (2)/ 2020-10-03 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site rash/ RASH ELBOW AREA INJECTION ARM	2020-10-05 (5)/ 2020-10-08 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3562142; Age (years): 53; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-15 (8)/ 2020-10-15 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562142; Age (years): 53; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 (8)/ 2020-10-15 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE	2020-10-15 (8)/ 2020-10-15 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 (8)/ 2020-10-17 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3562146; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (8)/ 2020-09-22 (13)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572004; Age (years): 69; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-08-17 23:00 (1)/ 2020-08-17 23:30 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572005; Age (years): 59; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOLS	2020-08-17 19:00 (1)/ 2020-08-22 10:00 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-01 (18)/ 2020-10-02 (19)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572007; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site warmth/ SKIN WARM @ INJECTION SITE	2020-08-18 16:00 (1)/ 2020-08-18 23:00 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572016; Age (years): 24; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gingival discomfort/ IRRITATED GUMS	2020-08-21 (3)/ 2020-08-23 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572023; Age (years): 39; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-21 (3)/ 2020-08-22 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572058; Age (years): 41; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPS	2020-09-23 09:00 (1)/ 2020-09-24 21:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572060; Age (years): 61; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site paraesthesia/ TINGLING IN INJECTION SITE ARM	2020-08-21 20:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3572073; Age (years): 20; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-30 (9)/ 2020-10-01 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-30 (9)/ 2020-10-01 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572139; Age (years): 35; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-02 (5)/ 2020-10-14 (17)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572156; Age (years): 19; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-01 (1)/ 2020-09-08 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-01 (1)/ 2020-09-08 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-01 (1)/ 2020-09-08 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572230; Age (years): 52; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (8)/ 2020-09-16 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572240; Age (years): 81; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-09-12 (4)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3582017; Age (years): 66; Sex: F; Race: MULTIPLE:				(b) (6)			
Infections and infestations/ Rhinitis/ INFECTIVE RHINITIS	2020-08-21 07:00 (1)/ 2020-08-23 13:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582029; Age (years): 40; Sex: M; Race: MULTIPLE:				(b) (6)			
Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING-GENERALIZED	2020-09-07 (15)/ 2020-09-11 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582035; Age (years): 41; Sex: F; Race: MULTIPLE:						(b) (6)	
Nervous system disorders/ Paraesthesia/ TINGLING SENSATION OF BOTH ARMS	2020-08-24 19:00 (1)/ 2020-08-26 19:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ TINGLING SENSATION OF BOTH ARMS	2020-09-21 19:00 (1)/ 2020-09-22 19:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582055; Age (years): 31; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATS	2020-08-27 01:30 (1)/ 2020-08-28 22:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-08-27 06:00 (1)/ 2020-08-28 20:00 (3)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582057; Age (years): 36; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-01 (6)/ 2020-09-02 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582080; Age (years): 37; Sex: M; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-01 10:00 (1)/ 2020-09-02 07:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582103; Age (years): 59; Sex: F; Race: MULTIPLE:				(b) (6)			
Nervous system disorders/ Hypogeusia/ DECREASED TASTE	2020-10-01 07:00 (1)/ 2020-10-01 11:00 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Hyposmia/ DECREASED SMELL	2020-10-01 07:00 (1)/ 2020-10-01 11:00 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582111; Age (years): 54; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Limb discomfort/ LEFT ARM DISCOMFORT	2020-10-09 11:00 (1)/	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	
Subject ID: US3582130; Age (years): 26; Sex: M; Race: MULTIPLE:						(b) (6)	
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-11 16:00 (2)/ 2020-09-18 10:04 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIAS	2020-10-10 (3)/ 2020-10-17 (10)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582130; Age (years): 26; Sex: M; Race: MULTIPLE:						(b) (6)	
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIAS (SHOULDER, KNEE)	2020-10-11 (4)/ 2020-10-16 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-13 (6)/ 2020-10-17 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582142; Age (years): 41; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	2020-10-15 (7)/ 2020-10-16 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582142; Age (years): 41; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-10-15 (7)/ 2020-10-16 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582145; Age (years): 28; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-10-09 17:30 (1)/ 2020-10-11 19:00 (3)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582182; Age (years): 63; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ WATERY STOOL	2020-10-17 (6)/ 2020-10-17 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602008; Age (years): 62; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING JOINT ACHES OR PAIN LOCATED IN BILATERAL SHOULDER AND HANDS	2020-09-09 (8)/ 2020-09-23 (22)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602010; Age (years): 44; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-03 18:00 (1)/ 2020-09-04 17:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602015; Age (years): 44; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA- FREQUENCY INREASED FROM HER BASELINE	2020-09-03 (1)/ 2020-09-17 19:51 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602015; Age (years): 44; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ TINGLING NUMBNESS TO THE LEFT FOREARM AND L THIGH	2020-09-03 22:30 (1)/ 2020-09-04 00:30 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ TINGLING NUMBNESS TO THE LEFT THIGH	2020-09-05 (3)/ 2020-09-07 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-08 (6)/ 2020-09-09 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-08 (6)/ 2020-09-11 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602015; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ HIGH TEMPERATURE THAN HER BASELINE, TMAX 99.1 NOT ASSOCIATED WITH COLD LIKE SYMPTOMS OR SWOLLEN GLANDS NOR HA NO WORSENING GI S/S	2020-09-10 (8)/ 2020-09-11 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVERISH (TEMPERATURE AT 99F)	2020-09-21 (19)/ 2020-09-24 (22)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602015; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-21 (19)/ 2020-09-25 (23)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-06 (6)/ 2020-10-07 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ SCRATCHY THROAT	2020-10-06 (6)/ 2020-10-08 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN							
General disorders and administration site conditions/ Swelling face/ SWELLING TO THE RIGHT SIDE OF THE FACE	2020-09-17 (7)/ 2020-09-27 (17)	Yes/ Yes/ No	2	Yes/6	R/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ TINGLING ON RIGHT SIDE OF FACE	2020-09-17 (7)/ 2020-09-28 (18)	Yes/ Yes/ No	2	Yes/6	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Immunisation anxiety related reaction/ ANXIETY RELATED TO THE VACCINE	2020-09-17 (7)/ 2020-10-07 (27)	Yes/ Yes/ No	2	Yes/6	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN							
General disorders and administration site conditions/ Feeling hot/ LEFT SIDED CHEST WALL WARMTH	2020-10-06 (26)/ 2020-10-16 (36)	Yes/ Yes/ No	2	Yes/4	R/ R	DOSE DELAYED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ LEFT SIDED TINGLING	2020-10-06 (26)/ 2020-10-16 (36)	Yes/ Yes/ No	2	Yes/4/6	R/ R	DOSE DELAYED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-18 (3)/ 2020-10-24 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Migraine/ MIGRAINE HEADACHE	2020-11-02 (18)/ 2020-11-03 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN							
Nervous system disorders/ Migraine/ MIGRAINE HEADACHE	2020-11-04 (20)/ 2020-11-04 (20)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602034; Age (years): 38; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SOME SWEATING	2020-11-01 (24)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3602039; Age (years): 55; Sex: M; Race: WHITE							
Nervous system disorders/ Paraesthesia/ FINGERTIP PARAESTHESIAS (BILATERAL, SYMMETRICAL)	2020-09-15 12:20 (1)/ 2020-09-15 12:45 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-14 07:00 (1)/ 2020-10-19 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602039; Age (years): 55; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ STOMACH CRAMPING	2020-10-21 (9)/ 2020-10-22 (10)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602051; Age (years): 52; Sex: M; Race: OTHER: OTHER RACE							
Injury, poisoning and procedural complications/ Procedural haemorrhage/ INCREASED BLEEDING INTRA OPERATIVE TIME	2020-10-29 (16)/ 2020-10-29 (16)	Yes/ Yes/ No	4	Yes/4	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602060; Age (years): 29; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-19 07:00 (1)/ 2020-09-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE (WORSENING IN AFTERNOON)	2020-09-19 07:00 (1)/ 2020-09-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602084; Age (years): 42; Sex: M; Race: OTHER: NOT SPECIFIED BY SUBJECT							
Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS	2020-10-22 (2)/ 2020-10-23 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Pruritus/ LEFT ARM PRUIRITIS	2020-10-22 08:00 (1)/ 2020-10-23 08:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602091; Age (years): 34; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Abdominal pain upper/ STOMACH ACHE	2020-10-21 18:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Feeling abnormal/ BRAIN FOG	2020-10-21 18:00 (1)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602120; Age (years): 58; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Axillary pain/ UNDERARM PAIN	2020-10-02 20:00 (1)/ 2020-10-07 07:00 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602123; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 07:00 (3)/ 2020-10-06 23:00 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Dyspepsia/ HEART BURN	2020-10-07 20:00 (6)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Nausea/ QUEASY STOMACH	2020-10-07 20:00 (6)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602123; Age (years): 46; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ SHOULDER PAIN L SIDED	2020-10-09 07:00 (7)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3602128; Age (years): 50; Sex: F; Race: OTHER: UNKNOWN							
Nervous system disorders/ Headache/ HEADACHE (INTERMITTENT, "ON AND OFF" AT LEAST 2X PER WEEK, EACH TIME LASTING 2 DAYS AND RELIEVED BY MEDICATION)	2020-10-07 (3)/ 2020-10-25 (21)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602131; Age (years): 39; Sex: M; Race: UNKNOWN							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE (L)	2020-10-06 17:00 (1)/ 2020-10-29 (24)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602131; Age (years): 39; Sex: M; Race: UNKNOWN							
General disorders and administration site conditions/ Injection site paraesthesia/ TINGLING AT INJECTION SITE (L)	2020-10-06 17:00 (1)/ 2020-10-29 (24)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE (L)	2020-10-06 17:00 (1)/ 2020-10-29 (24)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE (TIREDNESS)	2020-10-20 (15)/ 2020-10-21 (16)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602131; Age (years): 39; Sex: M; Race: UNKNOWN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 (15)/ 2020-10-21 (16)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ TINGLING SENSATION IN HIS CHEST (NO C/O CHEST PAIN OR SOB)	2020-10-28 (23)/ 2020-10-29 (24)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dysphonia/ THROAT HOARSENESS (NO FEVER OR PAIN)	2020-10-28 (23)/ 2020-10-29 (24)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602149; Age (years): 28; Sex: M; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATING	2020-10-30 (16)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602153; Age (years): 35; Sex: F; Race: UNKNOWN							
Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	2020-11-03 (20)/ 2020-11-08 (25)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATING	2020-11-06 (23)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3612040; Age (years): 51; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-15 (2)/ 2020-10-16 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622008; Age (years): 77; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ FULL BODY ITCHING	2020-09-15 (7)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622109; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-30 (2)/ 2020-08-31 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622114; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 (7)/ 2020-10-11 (13)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622127; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-11 (11)/ 2020-09-14 (14)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622138; Age (years): 59; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ FULL BODY PRURITUS	2020-10-01 (2)/ 2020-10-02 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622150; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-02 20:00 (1)/ 2020-10-20 (19)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHES	2020-10-02 20:00 (1)/ 2020-10-20 (19)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622161; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-05 17:30 (1)/ 2020-09-06 05:00 (1)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622199; Age (years): 43; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADED	2020-10-27 09:55 (1)/ 2020-10-27 11:30 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622216; Age (years): 51; Sex: F; Race: WHITE							
Nervous system disorders/ Taste disorder/ CHANGE OF TASTE	2020-09-22 19:00 (1)/ 2020-09-23 09:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632004; Age (years): 61; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-22 (5)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3632033; Age (years): 75; Sex: M; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS ON SECOND TOE ON LEFT FOOT	2020-09-27 (24)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3632048; Age (years): 53; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-01 13:30 (1)/ Ongoing	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632087; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ BRUISING AT INJECTION SITE	2020-09-23 (8)/ 2020-10-07 (22)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632090; Age (years): 71; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASM	2020-09-17 00:00 (1)/ 2020-09-24 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632091; Age (years): 29; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	2020-09-17 08:00 (1)/ 2020-09-19 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3642018; Age (years): 74; Sex: M; Race: WHITE							
Nervous system disorders/ Neuropathy peripheral/ NEUROPATHY	/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642042; Age (years): 71; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-26 (1)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3642057; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-28 (3)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3642060; Age (years): 68; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	2020-10-12 (15)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3642216; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ BRUISING AT INJECTION SITE	2020-09-16 (2)/ 2020-10-01 (17)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642276; Age (years): 19; Sex: M; Race: WHITE							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE IN MOUTH	2020-09-25 16:55 (1)/ 2020-09-25 17:18 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652004; Age (years): 67; Sex: M; Race: OTHER: PATIENT IDENTIFIED RACE AS OTHER							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING OR TENDERNESS (EDIARY)	2020-09-01 12:21 (1)/ 2020-09-15 23:59 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site bruising/ BRUISING AT INJECTION SITE LEFT ARM	2020-09-02 (2)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652009; Age (years): 65; Sex: M; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-12 (4)/ 2020-09-12 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-14 (6)/ 2020-09-15 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-14 (6)/ 2020-09-15 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652020; Age (years): 32; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE (EDIARY SYMPTOM)	2020-09-17 (7)/ 2020-09-22 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652021; Age (years): 32; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-12 15:02 (1)/ 2020-09-12 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3652056; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Feeling hot/ HEAT (L NECK)	2020-10-20 16:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652057; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE (EDIARY)	2020-10-23 (4)/ 2020-10-28 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE ALL OVER BODY (EDIARY)	2020-10-23 (4)/ 2020-10-28 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE (EDIARY)	2020-10-24 (5)/ 2020-10-28 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662006; Age (years): 50; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Hyperaesthesia teeth/ TOOTH SENSITIVITY TO TEMPERATURE CHANGES	2020-10-02 (5)/ 2020-10-10 (13)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Toothache/ TOOTH PAIN	2020-10-02 (5)/ 2020-10-17 (20)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662010; Age (years): 65; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymph node pain/ LEFT ARM LYMPH NODE TENDERNESS	2020-09-17 (8)/ 2020-09-17 (8)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymph node pain/ LEFT ARM LYMPH NODE TENDERNESS	2020-09-18 (9)/ 2020-09-25 (16)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662010; Age (years): 65; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-22 (13)/ 2020-09-24 (15)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ SCRATCHY THROAT	2020-09-22 (13)/ 2020-09-24 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymph node pain/ TENDERNESS OF LEFT LYMPH NODE	2020-10-10 (4)/ 2020-10-17 (11)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662026; Age (years): 24; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ PAIN AT STUDY MED INJECTION SITE, RIGHT DELTOID	2020-09-19 12:00 (1)/ 2020-09-28 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS, STUDY MED INJECTION SITE, RIGHT DELTOID. NON-URTICARIAL	2020-09-19 12:00 (1)/ 2020-10-05 (18)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662026; Age (years): 24; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site swelling/ SWELLING, STUDY MED INJECTION SITE, RIGHT DELTOID	2020-09-19 12:00 (1)/ 2020-10-05 (18)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymph node pain/ UNDERARM GLAND TENDERNESS, BILATERALY RIGHT & LEFT	2020-09-23 (6)/ 2020-10-25 (38)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES (ELBOWS AND KNEES)	2020-09-23 (6)/ 2020-11-01 (45)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662054; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-14 (7)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662071; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Axillary mass/ PEA SIZE SWOLLEN LUMP IN LEFT UNDERARM	2020-10-15 (4)/ 2020-10-27 (16)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Axillary mass/ REDNESS AT SWOLLEN LUMP IN LEFT UNDERARM	2020-10-15 (4)/ 2020-10-27 (16)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3662071; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Axillary mass/ WARMTH AT SWOLLEN LUMP IN LEFT UNDERARM	2020-10-15 (4)/ 2020-10-27 (16)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ UNDERARM RASH	2020-10-15 (4)/ 2020-10-29 (18)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662088; Age (years): 52; Sex: F; Race: ASIAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN LYMPHNODES	2020-09-29 (16)/ 2020-09-30 (17)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	2020-09-29 (16)/ 2020-09-30 (17)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3662088; Age (years): 52; Sex: F; Race: ASIAN							
Nervous system disorders/ Headache/ HEADACHES	2020-09-29 (16)/ 2020-09-30 (17)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662095; Age (years): 46; Sex: M; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING, SIDE OF FACE	2020-10-15 18:00 (1)/ 2020-10-15 18:05 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662096; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-14 18:00 (2)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES, DISSEMINATED	2020-10-14 18:00 (2)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662096; Age (years): 40; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES, DISSEMINATED	2020-10-14 18:00 (2)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-14 18:00 (2)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-14 18:00 (2)/ 2020-10-23 (11)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662104; Age (years): 22; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 16:00 (2)/ 2020-10-17 09:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662114; Age (years): 50; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-10-13 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662143; Age (years): 51; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-30 (2)/ 2020-09-30 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662147; Age (years): 29; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymph node pain/ LYMPH NODE TENDERNESS, AXILLARY, IPSILATERAL, ON SIDE OF INJECTION	2020-09-29 18:00 (1)/ 2020-10-10 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662180; Age (years): 64; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Pruritus/ DISSEMINATED MILD BODY ITCHING	2020-10-22 11:29 (1)/ 2020-10-23 23:59 (2)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-25 (4)/ 2020-10-25 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662180; Age (years): 64; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Pruritus/ DISSEMINATED MILD BODY ITCHING	2020-11-18 13:35 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662188; Age (years): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADNOPATHY UNDER RIGHT JAW	2020-10-24 07:30 (1)/ 2020-10-26 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenitis/ UNDER ARM SWELLING ON BOTH LYMPH NODES ON BOTH ARMS	2020-10-24 14:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662188; Age (years): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LYMPHADENOPATHY LEFT AXILLARY IPSILATERAL TO INJECTION SITE	2020-10-24 19:30 (2)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3672013; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-13 (8)/ 2020-08-20 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-08-13 (8)/ 2020-08-20 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672015; Age (years): 22; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-14 (6)/ 2020-09-17 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672023; Age (years): 42; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-10 (2)/ 2020-09-19 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672064; Age (years): 33; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BRAETH	2020-08-12 12:00 (1)/ 2020-08-24 12:00 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672071; Age (years): 48; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Discomfort/ RIGHT SIDED AXILLARY DISCOMFORT	2020-09-11 (2)/ 2020-09-20 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672097; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-19 (7)/ 2020-08-23 (11)	Yes/ No/ Yes	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672113; Age (years): 58; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-08-21 (8)/ 2020-08-24 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672113; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-21 (8)/ 2020-08-25 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672133; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (2)/ 2020-09-24 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672151; Age (years): 25; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH LOWER EXTREMITIES	2020-08-18 12:15 (1)/ 2020-08-26 (10)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672254; Age (years): 34; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-28 (8)/ 2020-09-29 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672268; Age (years): 38; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 (1)/ 2020-10-01 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymph node pain/ UNDERARM GLAND TENDERNESS	2020-09-28 (6)/ 2020-10-05 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672268; Age (years): 38; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ (GENERALIZED) JOINT ACHES	2020-09-28 (6)/ 2020-10-05 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672300; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ INTERMITTENT LEFT SHOULDER PAIN	2020-09-01 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHES	2020-09-01 (8)/ 2020-09-23 (30)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672300; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-01 (8)/ 2020-10-20 (57)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-01 (8)/ 2020-10-20 (57)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-09-01 (8)/ 2020-10-20 (57)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672300; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-03 12:59 (1)/ 2020-10-14 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-04 (3)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-10-04 (3)/ 2020-10-20 (19)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-10-04 (3)/ 2020-10-29 (28)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672300; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-04 (3)/ 2020-11-10 (40)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672328; Age (years): 64; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-30 (5)/ 2020-09-03 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672329; Age (years): 34; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-31 (6)/ 2020-09-03 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 (6)/ 2020-10-08 (15)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672332; Age (years): 29; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-04 (3)/ 2020-10-10 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672333; Age (years): 19; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY R UNDERARM	2020-09-07 (13)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3672391; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-05 (6)/ 2020-09-11 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672407; Age (years): 41; Sex: F; Race: WHITE							
Cardiac disorders/ Arrhythmia/ ARRHYTHMIA	2020-09-07 (5)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682008; Age (years): 36; Sex: F; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Musculoskeletal discomfort/ LEFT SHOULDER MUSCLE DISCOMFORT	2020-08-25 12:00 (1)/ 2020-09-08 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3682035; Age (years): 63; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-14 (17)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3682040; Age (years): 48; Sex: M; Race: OTHER: I DON'T KNOW HOW TO ANSWER							
Infections and infestations/ Varicella zoster virus infection/ EXACERBATION OF VARICELLA ZOSTER	2020-09-01 10:55 (1)/ 2020-10-03 (33)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682096; Age (years): 53; Sex: M; Race: NOT REPORTED							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-16 (6)/ 2020-09-18 (8)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3682126; Age (years): 38; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	2020-09-23 (8)/ 2020-09-25 (10)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3682139; Age (years): 33; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-30 (14)/ 2020-10-01 (15)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Asthenia/ WEAKNESS	2020-09-30 (14)/ 2020-10-04 (18)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682139; Age (years): 33; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-30 (14)/ 2020-10-04 (18)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3682180; Age (years): 69; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-09 (8)/ 2020-10-10 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3682197; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ LEFT DELTOID TENDERNESS	2020-10-25 (13)/ 2020-10-31 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT UPPER ARM PAIN	2020-11-18 (9)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682208; Age (years): 55; Sex: M; Race: OTHER: (b) (6)							
Metabolism and nutrition disorders/ Dyslipidaemia/ DYSLIPIDEMIA	2020-11-05 (21)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3692010; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ SITE OF INJECTION SITE RED- LEFT ARM-NON-URTICARIAL, NON-MACULAR, NON-PAPULAR	2020-09-13 (18)/ 2020-09-15 (20)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site mass/ SITE OF INJECTION RAISED-LEFT ARM (A LITTLE LUMP)	2020-09-13 (18)/ 2020-09-18 (23)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692052; Age (years): 72; Sex: M; Race: WHITE							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-09-04 12:34 (1)/ 2020-10-02 08:07 (28)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692059; Age (years): 69; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Tachypnoea/ TACHYPNEA	2020-09-05 13:22 (1)/ 2020-10-06 15:55 (32)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692088; Age (years): 56; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE-VERBAL REPORT	2020-09-11 08:00 (1)/ 2020-10-09 (30)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Diastolic hypertension/ DIASTOLIC HYPERTENSION	2020-10-08 (29)/ 2020-10-16 (37)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692094; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-12 08:00 (1)/ 2020-09-21 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ ALL OVER BODY AND MUSCLE ACHES	2020-09-12 08:00 (1)/ 2020-09-21 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692188; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-19 (7)/ 2020-10-20 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692199; Age (years): 35; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-12 09:51 (1)/ Ongoing	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702001; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Malaise/ MALAISE	2020-08-25 (1)/ 2020-08-26 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3702040; Age (years): 58; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN (EDIARY)	2020-09-25 (5)/ 2020-09-30 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722118; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SIITE (LEFT)	2020-08-08 (3)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722118; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-08 (3)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3722121; Age (years): 54; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-12 (7)/ 2020-08-13 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722157; Age (years): 39; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-15 (9)/ 2020-08-15 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-08 (5)/ 2020-09-08 (5)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722217; Age (years): 39; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES BILATERAL LEGS	2020-08-15 (4)/ 2020-08-22 (11)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722232; Age (years): 53; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-13 22:00 (1)/ 2020-08-22 21:00 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-15 (3)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3722245; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-15 (3)/ 2020-08-22 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722266; Age (years): 23; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-14 16:25 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3722315; Age (years): 35; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-22 (4)/ 2020-08-28 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722322; Age (years): 46; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN BILATERAL ELBOWS	2020-08-26 22:00 (1)/ 2020-09-02 21:00 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722338; Age (years): 73; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Peripheral swelling/ LEFT ARM SWELLING	2020-09-19 (3)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM PAIN	2020-09-19 (3)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3732036; Age (years): 75; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY LYMPHADENOPATHY - BILATERAL	2020-08-11 (2)/ 2020-08-19 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732049; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-18 (8)/ 2020-08-20 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732058; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-08-13 11:14 (1)/ 2020-08-13 11:18 (1)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732089; Age (years): 60; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-18 (4)/ 2020-09-28 (14)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-09-19 (5)/ 2020-09-28 (14)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732089; Age (years): 60; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-24 (10)/ 2020-09-28 (14)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732090; Age (years): 78; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-18 15:06 (1)/ 2020-10-05 (49)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Ecchymosis/ LEFT DELTOID ECCHYMOSIS	2020-08-19 (2)/ 2020-09-18 (32)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732198; Age (years): 65; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-29 (3)/ 2020-09-01 (6)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732252; Age (years): 72; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOIN ACHES IN SEVERAL JOINTS	2020-09-04 (4)/ 2020-09-14 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732304; Age (years): 55; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-10-08 (2)/ 2020-10-18 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732310; Age (years): 56; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-09-10 (1)/ 2020-09-17 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732376; Age (years): 50; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-26 (4)/ 2020-10-28 (6)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732387; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM SORENESS	2020-10-06 (1)/ 2020-10-15 (10)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ INTERMITTENT JOINT ACHES IN SEVERAL JOINTS	2020-10-07 (2)/ 2020-10-14 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ NON-MIGRAINE HEADACHE	2020-10-07 (2)/ 2020-10-15 (10)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732387; Age (years): 63; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-07 (2)/ 2020-10-20 (15)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742093; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 (5)/ 2020-10-05 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742109; Age (years): 31; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Vaccination site nodule/ 3 MM BENIGN NODULE AT VACCINATION SITE	2020-10-03 (10)/ 2020-10-11 (18)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742121; Age (years): 29; Sex: M; Race: MULTIPLE:						(b) (6)	
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 17:20 (1)/ 2020-09-11 12:01 (15)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-27 20:35 (1)/ 2020-09-05 14:52 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES [GENERALIZED]	2020-08-28 12:41 (1)/ 2020-09-05 14:52 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 08:27 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742174; Age (years): 43; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT AXILLARY LYMPHADEMOPATHY	2020-09-24 (25)/ 2020-09-27 (28)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Alopecia/ HAIR LOSS	2020-10-06 (9)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742236; Age (years): 22; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 16:06 (1)/ 2020-10-07 16:17 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742257; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE (KNEES)	2020-10-05 13:27 (1)/ 2020-10-25 (21)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742257; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-07 (3)/ 2020-10-14 (10)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-08 (4)/ 2020-10-18 (14)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742285; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site discomfort/ INJECTION SITE LEFT ARM HEAVINESS	2020-09-09 03:45 (1)/ 2020-09-09 14:00 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742301; Age (years): 45; Sex: F; Race: NOT REPORTED							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-09 12:41 (1)/ 2020-10-16 12:00 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-10 (3)/ 2020-10-16 (9)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	2020-10-14 (7)/ 2020-10-17 (10)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742341; Age (years): 50; Sex: M; Race: NOT REPORTED							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT PAIN	2020-09-12 05:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Nervous system disorders/ Paraesthesia/ PARASHESIAS RIGHT LEG	2020-09-12 05:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE DELAYED/ NONE	RECOVERING/ RESOLVING
Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS GENERALIZED	2020-09-12 05:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH	2020-09-12 05:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742341; Age (years): 50; Sex: M; Race: NOT REPORTED							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ DIAPHORESIS	2020-09-13 (3)/ 2020-09-17 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742363; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ BILATERAL HANDS, FEET, WRIST, ELBOW, SORENESS	2020-09-21 (5)/ 2020-10-09 (23)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Immune system disorders/ Serum sickness/ SERUM SICKNESS	2020-09-22 (6)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthritis/ POLYARTHRITIS ON L/R HANDS	2020-09-22 (6)/ Ongoing	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742363; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Onychomycosis/ FUNGAL TOE NAIL INFECTION	2020-10-11 (25)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Polyarthritis/ POLYARTHRITIS L/R FEET	2020-10-22 (8)/ Ongoing	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3742377; Age (years): 40; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-18 (5)/ 2020-10-27 (14)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742424; Age (years): 21; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-18 18:30 (1)/ 2020-09-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742424; Age (years): 21; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 18:30 (1)/ 2020-09-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742434; Age (years): 58; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-23 (5)/ 2020-09-29 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-17 17:25 (1)/ 2020-10-31 16:54 (15)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-17 17:25 (1)/ 2020-10-31 16:54 (15)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742441; Age (years): 33; Sex: F; Race: ASIAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-21 (5)/ 2020-10-25 (9)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742451; Age (years): 45; Sex: F; Race: NOT REPORTED							
Nervous system disorders/ Headache/ HEADACHE	2020-10-23 00:00 (1)/ 2020-11-04 (14)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT SWOLLEN UNDERARM GLAND	2020-10-23 17:43 (2)/ 2020-10-29 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-10-23 17:43 (2)/ 2020-11-06 (16)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742451; Age (years): 45; Sex: F; Race: NOT REPORTED							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ARMS AND FINGERS	2020-10-23 17:43 (2)/ 2020-11-06 (16)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742468; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-29 (7)/ 2020-10-02 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752001; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-10 (4)/ 2020-08-16 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752012; Age (years): 54; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-16 (10)/ 2020-08-22 (16)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752012; Age (years): 54; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE LASTING MORE THAN 48 HOURS	2020-08-16 (10)/ 2020-08-22 (16)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752033; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-10 (1)/ 2020-08-18 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-10 (1)/ 2020-09-27 (18)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752039; Age (years): 37; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-17 (7)/ 2020-08-20 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752091; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-12 (2)/ 2020-09-20 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-15 (5)/ 2020-09-15 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752096; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-20 (4)/ 2020-09-26 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752132; Age (years): 72; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-24 (7)/ 2020-08-26 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752180; Age (years): 57; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-25 (6)/ 2020-08-30 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-25 (6)/ 2020-08-31 (12)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-25 (6)/ 2020-09-01 (13)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752228; Age (years): 29; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-24 (1)/ 2020-09-02 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752229; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-28 (5)/ 2020-09-01 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752250; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ POST INJECTION SITE REDNESS OF LEFT ARM NONURTICARIAL	2020-08-30 (6)/ 2020-09-02 (9)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752251; Age (years): 47; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 07:00 (1)/ 2020-09-02 07:00 (8)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSOLATERAL AXILLARY LYMPHADENOPATHY	2020-08-30 (6)/ 2020-09-04 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ TENDERNESS AT INJECTION SITE	2020-08-30 (6)/ 2020-09-04 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752251; Age (years): 47; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-04 (11)/ 2020-10-07 (14)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-04 (11)/ 2020-10-07 (14)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSOLATERAL LYMPHADENOPATHY LEFT AXILLA	2020-10-05 (12)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752251; Age (years): 47; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Axillary pain/ LEFT AXILLARY SORENESS	2020-10-09 (16)/ 2020-10-12 (19)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752252; Age (years): 78; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-22 (1)/ 2020-10-05 (14)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752346; Age (years): 39; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-03 (3)/ 2020-09-10 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3762126; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-07 (40)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772094; Age (years): 46; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA (KNEES AND ELBOWS)	2020-08-19 (2)/ 2020-08-26 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA EXTREMITIES	2020-08-19 (2)/ 2020-08-27 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-19 (2)/ 2020-09-03 (17)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772094; Age (years): 46; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY GLAND SWELLING (IPSILATERAL)	2020-09-17 (1)/ 2020-09-26 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (1)/ 2020-09-26 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (2)/ 2020-09-26 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772145; Age (years): 31; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 (3)/ 2020-09-08 (16)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772149; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-24 (3)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3772159; Age (years): 76; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-28 (2)/ 2020-09-04 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-28 06:00 (1)/ 2020-09-04 06:00 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772159; Age (years): 76; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-08-30 (4)/ 2020-09-04 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-26 (2)/ 2020-10-03 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 (5)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772159; Age (years): 76; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-29 (5)/ 2020-10-03 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772175; Age (years): 75; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-04 (8)/ 2020-09-11 (15)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERAL MYLAGIA	2020-09-04 (8)/ 2020-09-11 (15)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772175; Age (years): 75; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 (6)/ 2020-10-23 (29)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772212; Age (years): 76; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-28 (1)/ 2020-10-08 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-28 (1)/ 2020-10-11 (14)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-28 19:57 (1)/ 2020-10-08 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772212; Age (years): 76; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 (2)/ 2020-10-08 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3782041; Age (years): 76; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ OCCASIONAL LEFT ARM PAIN (BELOW AND MEDIAL TO INJECTION SITE)	2020-09-20 (6)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3782073; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Malaise/ MALAISE	2020-08-28 (5)/ 2020-08-28 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782087; Age (years): 48; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-09 (16)/ 2020-09-14 (21)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-23 06:22 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3782116; Age (years): 35; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-29 20:44 (1)/ 2020-09-06 23:53 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782183; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 18:36 (1)/ 2020-10-23 17:55 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymph node pain/ UNDERARM GLAND TENDERNESS	2020-10-19 (4)/ 2020-10-23 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3792004; Age (years): 51; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ GROIN LYMPH GLAND SWELLING, LEFT	2020-08-14 (8)/ 2020-08-17 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3792004; Age (years): 51; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING, LEFT	2020-08-14 (8)/ 2020-08-17 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802016; Age (years): 37; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ BRUISING AT INJECTION SITE	2020-08-25 (6)/ 2020-08-28 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802023; Age (years): 71; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE	2020-08-26 (3)/ 2020-08-31 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802042; Age (years): 35; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Rash papular/ PAPULAR NON-URTICARIAL LEFT ARM RASH	2020-09-22 18:00 (1)/ 2020-10-19 07:00 (27)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3802109; Age (years): 22; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-12 (11)/ 2020-11-15 (45)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-12 (11)/ 2020-11-15 (45)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Fibromyalgia/ FIBROMYALGIA	2020-10-12 (11)/ 2020-11-15 (45)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802117; Age (years): 63; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY LEFT AXILLA	2020-10-13 (13)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3802135; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ BRUISE AT INJECTION SITE	2020-10-03 07:00 (1)/ 2020-10-09 17:00 (8)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Muscle tightness/ MUSCLE TIGHTNESS ON LEFT SIDE OF BODY	2020-10-04 (3)/ 2020-10-06 (5)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802135; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ LEFT SHOULDER, NECK AND CHEEK TINGLING	2020-10-18 (17)/ 2020-10-25 (24)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802144; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ BRUISING AT INJECTION SITE	2020-10-07 09:37 (1)/ 2020-10-08 12:00 (2)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802168; Age (years): 41; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Paraesthesia oral/ PINS AND NEEDLES FEELING IN MOUTH	2020-09-12 (5)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802172; Age (years): 63; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site bruising/ BRUISE AT INJECTION SITE	2020-10-09 14:50 (1)/ 2020-10-16 07:00 (7)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802191; Age (years): 25; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ BRUISE AT INJECTION SITE	2020-10-07 08:00 (1)/ 2020-10-12 17:00 (7)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802194; Age (years): 39; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ MIGRAINES	2020-10-03 (24)/ 2020-10-05 (26)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802233; Age (years): 41; Sex: F; Race: WHITE							
Immune system disorders/ Hypersensitivity/ UNSPECIFIED ALLERGIC REACTION, MILD, AND WITHOUT SIGNIFICANT SOFT TISSUE SWELLING OR AIRWAY COMPROMISE - SWOLLEN EARS, TINGLING TONGUE AND LIPS	2020-10-15 (4)/ 2020-10-28 (17)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3802234; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-21 (8)/ 2020-11-01 (19)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802251; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-15 09:30 (1)/ 2020-09-23 18:00 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802251; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-27 (12)/ 2020-10-29 (14)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812020; Age (years): 34; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Irritable bowel syndrome/ WORSENING IRRITABLE BOWEL SYNDROME	2020-08-04 15:45 (1)/ 2020-09-01 10:00 (29)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812199; Age (years): 75; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ LEFT ARM SWELLING AT INJECTION SITE	2020-09-17 (1)/ 2020-10-01 (15)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812266; Age (years): 34; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ CHIPPED WISDOM TOOTH	2020-09-25 (3)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812315; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASM LEFT SHOULDER	2020-10-09 (8)/ 2020-10-15 (14)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812343; Age (years): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-27 (4)/ 2020-10-05 (12)	Yes/ Yes/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822006; Age (years): 51; Sex: F; Race: WHITE							
Eye disorders/ Eye swelling/ SWELLING UNDER EYE, BILATERAL	2020-08-09 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822011; Age (years): 42; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ FACIAL RASH, UNKNOWN TYPE	2020-08-14 (10)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822041; Age (years): 34; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-02 (1)/ 2020-09-11 (10)	Yes/ No/ Yes	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822053; Age (years): 40; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Swelling/ UNDER ARM SWELLING SAME SIDE AS VACCINE	2020-08-20 (11)/ 2020-08-21 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822057; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 (1)/ 2020-09-22 (14)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA EXACERBATION	2020-09-09 19:00 (1)/ 2020-09-10 00:00 (1)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-10 (2)/ 2020-09-17 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822154; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIQUE	2020-09-14 00:00 (28)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-14 00:00 (28)/ 2020-09-21 23:59 (36)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822158; Age (years): 26; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (2)/ 2020-09-26 (10)	Yes/ No/ Yes	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-18 11:45 (1)/ 2020-09-25 07:00 (8)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822178; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS	2020-09-23 00:00 (36)/ 2020-09-23 12:00 (36)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822187; Age (years): 64; Sex: M; Race: NOT REPORTED							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA, GENERALIZED	2020-09-24 00:00 (36)/ 2020-10-05 07:00 (47)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822219; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-19 00:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822347; Age (years): 40; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Paraesthesia oral/ TINGLING ON LIPS	2020-09-02 00:00 (1)/ 2020-09-04 12:00 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822386; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-20 06:30 (9)/ 2020-09-20 07:30 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822402; Age (years): 52; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-21 (5)/ 2020-09-21 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822414; Age (years): 78; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood glucose increased/ INCREASE IN BLOOD GLUCOSE FOR 3 DAYS	2020-09-21 17:00 (1)/ 2020-09-24 07:00 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-22 (2)/ 2020-09-23 07:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822418; Age (years): 36; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 00:00 (4)/ 2020-09-28 23:59 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3842028; Age (years): 30; Sex: F; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Acne/ ACNE	2020-11-06 (30)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3842029; Age (years): 59; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-14 (5)/ 2020-09-17 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3842047; Age (years): 49; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (8)/ 2020-10-03 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3842047; Age (years): 49; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-02 (8)/ 2020-10-03 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852004; Age (years): 70; Sex: F; Race: WHITE							
Vascular disorders/ Hot flush/ HOT FLASH	2020-08-22 12:00 (2)/ 2020-08-22 12:30 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852005; Age (years): 67; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-16 12:15 (1)/ 2020-09-16 18:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852022; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ SORE BACK FROM GARDENING	2020-09-07 (14)/ 2020-10-28 (65)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852096; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ Oral herpes/ FEVER BLISTER	2020-09-05 (3)/ 2020-09-06 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site paraesthesia/ TINGLING/NERVE SENSATIONS IN INJECTION ARM	2020-10-03 (4)/ 2020-10-12 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852111; Age (years): 34; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-06 (3)/ 2020-09-08 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852111; Age (years): 34; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Tonsillar inflammation/ INFLAMED TONSILS	2020-09-06 (3)/ 2020-09-08 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852140; Age (years): 73; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-06 11:00 (2)/ 2020-10-07 12:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-10-07 (3)/ 2020-10-13 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852176; Age (years): 31; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE JOINT PAIN	2020-09-13 (3)/ 2020-09-15 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862022; Age (years): 65; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Joint range of motion decreased/ DECREASED ROM [LEFT ARM]	2020-09-18 (5)/ 2020-09-18 (5)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3862116; Age (years): 72; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-04 (3)/ 2020-09-10 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-04 (3)/ 2020-09-11 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862116; Age (years): 72; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BODY JOINT ACHES	2020-09-05 (4)/ 2020-09-12 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ BODY MUSCLE ACHES	2020-09-05 (4)/ 2020-09-12 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862172; Age (years): 32; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-11 23:20 (1)/ 2020-09-25 08:30 (14)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862255; Age (years): 51; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-10-28 00:01 (1)/ 2020-10-28 01:00 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862276; Age (years): 48; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES IN UPPER AND LOWER BACK, RIGHT LEG, BILATERAL ARMS AND SHOULDERS, AND HAND AREA	2020-10-02 13:41 (1)/ 2020-10-18 09:30 (17)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872031; Age (years): 57; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ EXACERBATION HEADACHE (MODERATE)	2020-09-02 11:00 (1)/ 2020-09-13 (13)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS ALL OVER BODY	2020-09-03 (3)/ 2020-09-06 (6)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872031; Age (years): 57; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ BRUISING ALL OVER BODY	2020-09-04 (4)/ 2020-09-08 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ MODERATE FATIGUE	2020-09-07 (7)/ 2020-09-13 (13)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ MILD HEADACHE	2020-09-14 (14)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3872062; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM TENDERNESS	2020-09-28 (27)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872072; Age (years): 76; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-08 (3)/ 2020-08-17 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dysphonia/ INTERMITTENT VOICE STRAIN	2020-08-08 (3)/ 2020-08-30 (25)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ INTERMITTENT RUNNY NOSE	2020-08-08 (3)/ 2020-09-01 (27)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872072; Age (years): 76; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dysphonia/ VOICE CRACKING	2020-09-06 (4)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3872172; Age (years): 64; Sex: F; Race: WHITE							
Vascular disorders/ Hot flush/ WORSENING OF HOT FLASHES	2020-08-15 (3)/ Ongoing	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3892056; Age (years): 64; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ LEFT DELTOID PAIN	2020-10-09 (8)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	
Subject ID: US3892077; Age (years): 23; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-12 (2)/ 2020-09-16 (6)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3902009; Age (years): 47; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES GENERALIZED	2020-09-28 (28)/ 2020-10-12 (42)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Peripheral swelling/ BILATERAL HAND SWELLING	2020-10-04 (4)/ 2020-10-12 (12)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ BILATERAL HAND PAIN	2020-10-04 (4)/ 2020-10-12 (12)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3902019; Age (years): 61; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON BUTTOCKS AND BILATERAL AXILLA	2020-09-05 (4)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthralgia/ SORENESS IN JOINTS - BILATERAL HIPS	2020-10-05 (34)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3902042; Age (years): 80; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Productive cough/ PLEGM BUILD UP	2020-10-10 (5)/ 2020-10-12 (7)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3912006; Age (years): 71; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION- GRADE 3	2020-08-26 12:51 (1)/ 2020-08-26 14:05 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912020; Age (years): 57; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT ARM UNDERARM LYMPHADENOPATHY, IPSILATERAL	2020-09-07 (11)/ 2020-09-10 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-28 (4)/ 2020-10-03 (9)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-28 (4)/ 2020-10-03 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3912026; Age (years): 72; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-28 15:03 (1)/ 2020-08-29 08:15 (1)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-29 02:43 (1)/ 2020-09-24 20:54 (28)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION (GRADE 3)	2020-09-25 11:42 (1)/ 2020-09-25 11:54 (1)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912032; Age (years): 22; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-04 (7)/ 2020-10-06 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3912052; Age (years): 73; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-03 (6)/ 2020-10-06 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912058; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION (WORSENING OF)	2020-09-01 12:55 (1)/ 2020-09-01 13:11 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-04 (4)/ 2020-09-09 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-04 (4)/ 2020-09-14 (14)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912059; Age (years): 32; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ STINGING AT INJECTION SITE	2020-09-01 12:31 (1)/ 2020-09-01 18:00 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912067; Age (years): 63; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-01 16:13 (1)/ 2020-10-27 (57)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912099; Age (years): 73; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-03 (1)/ 2020-09-12 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912099; Age (years): 73; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-05 (3)/ 2020-09-12 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-07 (5)/ 2020-09-12 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-08 (6)/ 2020-09-12 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912111; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION-GRADE 3	2020-10-01 13:42 (1)/ 2020-10-01 13:52 (1)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912111; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE	2020-10-08 (8)/ 2020-10-10 (10)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE LEFT AXILLARY LYMPHADENOPATHY	2020-10-11 (11)/ 2020-10-15 (15)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Axillary pain/ PAIN LEFT ARMPIT	2020-10-11 (11)/ 2020-10-21 (21)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912118; Age (years): 69; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-08 11:37 (1)/ 2020-09-08 14:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-06 12:20 (1)/ 2020-10-06 14:44 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912151; Age (years): 29; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING OR TENDERNESS	2020-10-14 (6)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ BILATERAL UNDERARM RASH	2020-10-14 (6)/ 2020-11-08 (31)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912161; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 (3)/ 2020-10-21 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912163; Age (years): 43; Sex: M; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-15 17:00 (1)/ 2020-09-16 18:00 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912170; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-23 20:29 (1)/ 2020-10-02 17:44 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-28 (6)/ 2020-10-06 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912228; Age (years): 46; Sex: F; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-01 (2)/ 2020-10-18 (19)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-01 (2)/ 2020-10-18 (19)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912233; Age (years): 30; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-08 12:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-08 12:00 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912233; Age (years): 30; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-09 12:00 (2)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-10-16 (9)/ 2020-10-19 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912241; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Asthenia/ GENERALIZED WEAKNESS	2020-11-03 (23)/ Ongoing	Yes/ Yes/ No	4	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ CHEST PAIN (PLEURAL)	2020-11-03 (23)/ 2020-11-05 (25)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912241; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM, LLL	2020-11-03 (23)/ 2020-11-09 (29)	Yes/ Yes/ No	4	Yes/3 (2020-11-04/ 2020-11-05)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3922051; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 (2)/ 2020-10-05 (4)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3922093; Age (years): 50; Sex: M; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-10-09 11:33 (1)/ 2020-10-09 12:10 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932003; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-09 (16)/ 2020-09-16 (23)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-09 (16)/ 2020-09-20 (27)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 (16)/ 2020-09-20 (27)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932025; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-02 (5)/ 2020-09-04 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932025; Age (years): 51; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ FLU LIKE SYMPTOMS - NASAL CONGESTION	2020-10-11 (16)/ 2020-10-16 (21)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3932040; Age (years): 29; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-28 07:00 (28)/ 2020-09-30 08:00 (30)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-28 07:00 (28)/ 2020-09-30 08:00 (30)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932136; Age (years): 34; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-15 22:39 (1)/ 2020-09-23 00:25 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932147; Age (years): 84; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ BODY ACHES/ MUSCLE ACHES	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932147; Age (years): 84; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ CONGESTION/ RUNNY NOSE	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932201; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ INTERMITTENT FATIGUE	2020-09-29 (4)/	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932204; Age (years): 21; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-09-28 22:04 (1)/ 2020-10-07 11:59 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ INTERMITTENT FATIGUE	2020-09-30 (3)/ 2020-10-07 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932281; Age (years): 59; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHES	2020-10-16 16:00 (1)/ 2020-10-23 12:00 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Paraesthesia oral/ LIP TINGLING	2020-10-17 08:00 (1)/ 2020-10-23 08:00 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932289; Age (years): 78; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-12 12:53 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-12 18:19 (1)/ 2020-11-21 18:18 (10)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952027; Age (years): 76; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED GRADE 3 BLOOD PRESSURE	2020-10-01 15:09 (1)/ 2020-10-01 15:19 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3952110; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ BILATERAL POSTERIOR LEG PAIN	2020-10-26 (6)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3952156; Age (years): 36; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATS	2020-11-02 (4)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3962004; Age (years): 46; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site haemorrhage/ ECCHYMOSIS AT INJECTION SITE	2020-08-24 (7)/ 2020-09-22 (36)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962016; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 (1)/ 2020-10-02 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (1)/ 2020-10-02 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-30 (7)/ 2020-10-02 (9)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3962065; Age (years): 54; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-10-07 (3)/ 2020-10-14 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962084; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ SMALL BRUISE AT INJECTION SITE	2020-09-24 (17)/ 2020-09-26 (19)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3972040; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCH ON SITE OF INJECTION	2020-08-27 14:30 (1)/ 2020-09-09 16:30 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3982034; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA, INTERMITTENT	2020-10-01 (4)/ 2020-10-10 (13)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982034; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (5)/ 2020-10-10 (13)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3982059; Age (years): 72; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Salivary hypersecretion/ EXCESS SALIVATION	2020-08-31 17:30 (1)/ 2020-08-31 22:30 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-08-31 17:30 (1)/ 2020-08-31 22:30 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Salivary hypersecretion/ EXCESS SALIVATION	2020-09-28 10:15 (1)/ 2020-09-28 12:15 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982143; Age (years): 44; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIAS (ALL OVER THE BODY)	2020-09-09 21:50 (1)/ 2020-09-17 12:05 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ NEW HEADACHES-NOT MIGRAINE	2020-09-09 21:50 (1)/ 2020-09-17 17:00 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 21:50 (1)/ 2020-09-20 16:41 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982143; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BURNING PAIN IN HANDS	2020-09-10 13:04 (1)/ 2020-09-17 12:05 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3992064; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	2020-10-12 (8)/ 2020-10-13 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-12 (8)/ 2020-10-13 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002023; Age (years): 32; Sex: M; Race: WHITE							
Nervous system disorders/ Paraesthesia/ PARESTHESIA OF LEFT DELTOID	2020-08-28 (4)/ 2020-09-17 00:00 (23)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3002040; Age (years): 44; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERAL MUSCLE ACHES	2020-08-26 (1)/ 2020-09-03 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002111; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-08 13:38 (1)/ 2020-09-15 12:09 (8)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002111; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-09 12:02 (2)/ 2020-09-15 12:09 (8)	Yes/ No/ Yes	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3002135; Age (years): 27; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT AXILLARY LYMPHADENOPATHY	2020-08-07 (1)/ 2020-10-08 00:00 (62)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3002207; Age (years): 45; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-08-29 (2)/ 2020-08-29 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002221; Age (years): 67; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-02 (3)/ 2020-09-12 (13)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3002293; Age (years): 40; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE LEFT AXILLARY LYMPHADENOPATHY	2020-09-17 (7)/ 2020-09-19 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3002327; Age (years): 54; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Dysgeusia/ DYSGEUSIA	2020-09-25 13:00 (1)/ 2020-09-25 13:07 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002327; Age (years): 54; Sex: F; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ PALMAR HYPERHIDROSIS (BILATERAL PALMS)	2020-09-25 13:00 (1)/ 2020-09-25 13:07 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012004; Age (years): 64; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-07-28 (2)/ 2020-08-02 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-07-28 08:00 (1)/ 2020-07-29 12:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012016; Age (years): 54; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 (2)/ 2020-09-02 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012021; Age (years): 46; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ SCRATCHY THROAT	2020-07-29 06:30 (1)/ 2020-07-30 06:30 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-27 03:00 (1)/ 2020-08-27 03:02 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012023; Age (years): 29; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE, LEFT ARM	2020-08-25 21:00 (1)/ 2020-09-02 (9)	Yes/ Yes/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Investigations/ Heart rate irregular/ IRREGULAR HEART RATE	2020-08-26 16:00 (2)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012039; Age (years): 59; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-04 05:30 (7)/ 2020-09-12 08:00 (15)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012053; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE, LEFT ARM	2020-08-06 16:00 (1)/ 2020-08-26 (21)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012056; Age (years): 37; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 (7)/ 2020-09-11 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012059; Age (years): 68; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-08-09 (4)/ 2020-08-13 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012068; Age (years): 53; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE, LEFT	2020-08-06 (1)/ 2020-08-15 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-06 (1)/ 2020-08-17 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012107; Age (years): 65; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-08-17 (7)/ 2020-08-19 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012107; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-18 (8)/ 2020-08-22 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012158; Age (years): 25; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-23 (7)/ 2020-08-25 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-23 (7)/ 2020-08-25 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012159; Age (years): 34; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-17 17:00 (1)/ 2020-08-26 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012173; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ TINGLING SENSATION	2020-09-16 00:30 (1)/ 2020-09-16 03:00 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012217; Age (years): 67; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ CRACKED LEFT UPPER MOLAR #3	2020-10-02 (12)/ 2020-10-09 (19)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012232; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Tenderness/ UNDERARM TENDERNESS, LEFT	2020-09-01 (7)/ 2020-09-05 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012232; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN @ INJECTION SITE	2020-09-02 (8)/ 2020-09-05 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012240; Age (years): 36; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE LEFT SIDE	2020-08-28 15:00 (1)/ 2020-09-11 07:00 (14)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012293; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Axillary pain/ UNDERARM TENDERNESS	2020-09-15 (5)/ 2020-09-19 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012293; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (7)/ 2020-09-19 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012309; Age (years): 64; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-17 (4)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022038; Age (years): 73; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-07-29 12:08 (2)/ 2020-08-05 09:00 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022038; Age (years): 73; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER	2020-07-30 (3)/ 2020-08-05 (9)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022062; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-04 (7)/ 2020-08-07 (10)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-04 (7)/ 2020-08-12 (15)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022086; Age (years): 86; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Hypoaesthesia oral/ NUMBNESS OF TONGUE	2020-07-30 17:50 (1)/ 2020-07-30 18:10 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022127; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-12 (7)/ 2020-08-16 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER	2020-08-12 (7)/ 2020-08-17 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022175; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-20 00:00 (1)/ 2020-08-20 11:59 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022187; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-21 17:36 (1)/ 2020-09-29 09:00 (8)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022242; Age (years): 59; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-25 (5)/ 2020-08-29 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022270; Age (years): 18; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-22 00:00 (1)/ 2020-08-22 11:59 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032042; Age (years): 52; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ CERVICALGIA (NECK PAIN)	2020-08-10 (13)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032086; Age (years): 73; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMA LEFT UPPER ARM, NON-UTICARIAL	2020-08-13 (10)/ 2020-08-15 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3032131; Age (years): 41; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMA OF LEFT UPPER ARM	2020-08-16 10:00 (10)/ 2020-08-22 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3032138; Age (years): 45; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMA OF LEFT UPPER ARM	2020-08-15 (9)/ 2020-08-20 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042090; Age (years): 55; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERAL MUSCLE ACHES	2020-08-11 (6)/ 2020-08-18 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-11 (6)/ 2020-09-02 (28)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-08-14 (9)/ 2020-08-19 (14)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042090; Age (years): 55; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERAL MUSCLE ACHES	2020-09-07 (5)/ 2020-09-10 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-07 (5)/ 2020-09-18 (16)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3042157; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE-LEFT SIDE AXILLARY LYMPHADENOPATHY	2020-08-14 (3)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042251; Age (years): 39; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ MILD NASAL CONGESTION	2020-09-16 (1)/ 2020-09-20 (5)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3052014; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-25 18:00 (1)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Skin and subcutaneous tissue disorders/ Erythema/ LOCALIZED REDNESS	2020-08-25 18:00 (1)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3052034; Age (years): 52; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-07-31 20:34 (1)/ 2020-08-09 19:19 (10)	Yes/ No/ Yes	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3052258; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3052262; Age (years): 35; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Adverse drug reaction/ ADVERSE EFFECT OF DRUG	2020-09-18 19:00 (1)/ 2020-09-24 08:00 (6)	Yes/ Yes/ No	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062047; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES GENERALIZED	2020-08-04 06:00 (1)/ 2020-08-12 23:00 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062047; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES GENERALIZED	2020-08-04 06:00 (1)/ 2020-08-12 23:00 (10)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-08 (6)/ 2020-08-12 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3062107; Age (years): 50; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	2020-08-08 (4)/ 2020-08-21 (17)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062141; Age (years): 65; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-08 12:00 (2)/ 2020-08-14 (8)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062213; Age (years): 73; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 14:00 (2)/ 2020-09-16 23:00 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062250; Age (years): 39; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-20 (6)/ 2020-08-25 (11)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3062292; Age (years): 28; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE	2020-10-01 15:00 (1)/ 2020-10-09 19:00 (10)	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062300; Age (years): 37; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-06 09:00 (1)/ 2020-09-21 (17)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE NON URTICARIAL	2020-09-15 (11)/ 2020-09-17 (13)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082026; Age (years): 34; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-08-14 09:00 (1)/ 2020-08-24 20:00 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082040; Age (years): 47; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ SHOULDER AND NECK PAIN ON SIDE OF INJECTION	2020-08-19 (3)/ 2020-08-22 (6)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082045; Age (years): 36; Sex: M; Race: WHITE							
Eye disorders/ Visual impairment/ VISUAL DISTURBANCE	2020-09-15 16:40 (1)/ 2020-09-15 16:50 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dysgeusia/ METALLIC TASTE	2020-09-15 16:40 (1)/ 2020-09-15 16:50 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082078; Age (years): 39; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ AXILLARY LYMPHADENOPATHY IPSILATERAL TO INJECTION SITE	2020-08-21 (1)/ 2020-09-05 07:00 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082081; Age (years): 66; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ HIVES	2020-10-01 (11)/ 2020-10-05 (15)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082082; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (MACULOPAPULAR AND NON-URTICARIAL)	2020-08-27 (7)/ 2020-08-31 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082101; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-24 (3)/ 2020-09-27 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082120; Age (years): 71; Sex: M; Race: UNKNOWN							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-29 07:00 (1)/ 2020-09-30 07:00 (2)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082129; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (MACULOPAPULAR AND NON-URTICARIAL)	2020-09-03 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082140; Age (years): 67; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ MUSCLE PAIN [LEFT FOREARM, SIDE OF INJECTION]	2020-10-17 (19)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3082159; Age (years): 38; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-01 02:00 (1)/ 2020-09-01 04:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082180; Age (years): 52; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-11 (10)/ Ongoing	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082180; Age (years): 52; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-11 (10)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3082187; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-11 (9)/ 2020-09-13 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082192; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-12 (10)/ 2020-09-24 (22)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082196; Age (years): 73; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-10-09 (4)/ 2020-10-12 (7)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082215; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-18 (10)/ 2020-09-20 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082224; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE ITCHING	2020-09-18 (9)/ 2020-10-15 (36)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082226; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site warmth/ WARM INJECTION SITE	2020-09-11 02:30 (1)/ 2020-09-13 15:00 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082246; Age (years): 49; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Chapped lips/ DRY/CRACKED LIPS	2020-09-16 08:00 (1)/ 2020-09-21 08:00 (6)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3092007; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM SORENESS	2020-08-04 12:47 (1)/ 2020-08-06 12:47 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3092110; Age (years): 44; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHES	2020-09-14 (1)/ 2020-09-21 (8)	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092110; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-14 (1)/ 2020-09-22 (9)	Yes/ Yes/ Yes	1	No	R/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-14 (1)/ 2020-09-26 (13)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	UNKNOWN
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-15 (2)/ 2020-09-26 (13)	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3092112; Age (years): 68; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-15 (36)/ Ongoing	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092112; Age (years): 68; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-15 (36)/ 2020-09-17 (38)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3092207; Age (years): 35; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ MUSCLE PAIN AT INJECTION SITE	2020-09-21 (1)/ 2020-11-02 (43)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3092297; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-14 (16)/ 2020-10-20 (22)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102347; Age (years): 56; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ PAIN @ INJ SITE	2020-10-09 (1)/ 2020-10-11 (3)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112011; Age (years): 70; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Axillary pain/ LEFT UNDERARM TENDERNESS	2020-07-31 (3)/ 2020-08-12 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112046; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-08-01 19:00 (2)/ 2020-08-02 09:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-01 19:00 (2)/ 2020-08-02 09:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112046; Age (years): 45; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH LOWER BACK-NON-URTICARIAL	2020-08-28 20:00 (1)/ 2020-09-03 (7)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Limb discomfort/ LEFT LEG HEAVINESS	2020-08-31 (4)/ 2020-09-05 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Limb discomfort/ LEFT LEG HEAVINESS WITH NUMBNESS	2020-08-31 (4)/ 2020-09-05 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112046; Age (years): 45; Sex: F; Race: WHITE							
Nervous system disorders/ Sciatica/ LEFT LEG HEAVINESS WITH TINGLING (SCIATICA)	2020-08-31 (4)/ 2020-09-05 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112097; Age (years): 48; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT UNDERARM SWELLING/TENDERNESS	2020-08-06 (3)/ 2020-08-12 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112296; Age (years): 64; Sex: M; Race: WHITE							
Nervous system disorders/ Dysgeusia/ DYSGEUSIA	2020-08-18 20:00 (1)/ 2020-08-23 07:00 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dysgeusia/ DYSGEUSIA	2020-09-16 15:00 (1)/ 2020-09-21 07:00 (5)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112298; Age (years): 40; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-19 (2)/ 2020-08-22 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112343; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-23 (3)/ 2020-09-05 (16)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-25 (5)/ 2020-08-28 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112354; Age (years): 71; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-25 07:00 (1)/ 2020-10-02 (9)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112354; Age (years): 71; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-25 07:00 (1)/ 2020-10-04 (11)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112360; Age (years): 43; Sex: F; Race: WHITE							
Nervous system disorders/ Hyperaesthesia/ TACTILE HYPERESTHESIA	2020-09-21 19:01 (1)/ 2020-09-22 23:00 (2)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3122022; Age (years): 47; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-07-27 20:30 (1)/ 2020-07-28 20:30 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Neck pain/ POSTERIOR NECK PAIN	2020-09-05 (12)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122024; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 00:00 (31)/ 2020-08-30 23:59 (35)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-27 00:00 (31)/ 2020-08-30 23:59 (35)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-08-27 00:00 (31)/ 2020-08-30 23:59 (35)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 00:00 (31)/ 2020-08-30 23:59 (35)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122027; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-08-25 00:00 (29)/ 2020-08-26 23:59 (31)	Yes/ No/ No	2	No	R/ R	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-08-25 00:00 (29)/ 2020-08-26 23:59 (31)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-25 00:00 (29)/ 2020-08-26 23:59 (31)	Yes/ No/ No	2	No	R/ R	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122047; Age (years): 28; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ HYPERSENSITIVITY RASH - BILATERAL ELBOWS (MACULAR - URTICARIAL)	2020-08-04 (9)/ 2020-08-11 (16)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3122062; Age (years): 37; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE/BODY ACHES	2020-07-29 00:00 (1)/ 2020-07-31 23:59 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-29 (4)/ 2020-08-30 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122066; Age (years): 76; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-28 00:00 (1)/ 2020-08-29 23:59 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122071; Age (years): 52; Sex: F; Race: NOT REPORTED							
Vascular disorders/ Deep vein thrombosis/ DEEP VEIN THROMBOSIS (L-CALF)	2020-09-22 (27)/ Ongoing	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3122092; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE SORENESS	2020-08-26 00:00 (28)/ 2020-08-28 23:59 (31)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122111; Age (years): 47; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE MUSCLE PAIN	2020-08-27 00:00 (29)/ 2020-10-01 23:59 (65)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122112; Age (years): 23; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-26 09:00 (28)/ 2020-08-26 23:59 (29)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122128; Age (years): 64; Sex: M; Race: WHITE							
Nervous system disorders/ Movement disorder/ DIFFICULTY RAISING LEFT ARM	2020-07-30 00:00 (1)/ 2020-08-01 23:59 (4)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3122130; Age (years): 48; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-07-30 00:00 (1)/ 2020-07-30 23:59 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122130; Age (years): 48; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ TINGLING IN LOWER LEFT LEG	2020-07-30 00:00 (1)/ 2020-07-30 23:59 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3122133; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-01 (3)/ 2020-08-02 (4)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122145; Age (years): 63; Sex: F; Race: WHITE							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE IN MOUTH	2020-09-30 00:00 (1)/ 2020-10-01 23:59 (3)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-30 00:00 (1)/ 2020-10-01 23:59 (3)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3132004; Age (years): 52; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Costochondritis/ LEFT SIDE COSTCOCHONDRITIS	2020-08-31 16:00 (1)/ 2020-08-31 20:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3132048; Age (years): 55; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Axillary pain/ LEFT UNDERARM PAIN	2020-09-18 (5)/ 2020-09-22 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3132060; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site scab/ SCAB ON LEFT ARM AT INJECTION SITE	2020-09-19 (4)/ 2020-09-28 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3132132; Age (years): 50; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Axillary mass/ LUMP LEFT ARMPIT	2020-10-17 (2)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ ACID REFLUX	2020-10-17 (2)/ 2020-11-07 (23)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152004; Age (years): 29; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-07-28 (2)/ 2020-07-28 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152014; Age (years): 66; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-09 (13)/ 2020-08-11 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152018; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
Vascular disorders/ Flushing/ FACIAL FLUSHING	2020-08-04 (8)/ 2020-08-04 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-04 (8)/ 2020-08-05 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152026; Age (years): 67; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dyspepsia/ INDIGESTION	2020-08-04 (7)/ 2020-08-05 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-08 (8)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152026; Age (years): 67; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-09-08 (8)/ 2020-09-22 (22)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-08 (8)/ 2020-10-14 (44)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-16 (16)/ 2020-09-16 (16)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152032; Age (years): 70; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-10 (3)/ 2020-09-12 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152041; Age (years): 62; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-03 (5)/ 2020-08-04 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-08 (10)/ 2020-08-08 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-13 (15)/ 2020-08-13 (15)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP PAIN	2020-09-04 (4)/ 2020-09-04 (4)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152043; Age (years): 69; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES BILATERAL LEGS	2020-08-10 (12)/ Ongoing	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152067; Age (years): 43; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT ENLARGED SUPRACLAVICULAR LYMPHADENOPATHY, IPSILATERAL	2020-08-04 (5)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY LYMPH NODE SWELLING/TENDERNESS, IPSILATERAL	2020-08-08 (9)/ 2020-08-09 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152067; Age (years): 43; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-08-08 (9)/ 2020-08-09 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152077; Age (years): 54; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY GLAND SWELLING	2020-09-08 (8)/ 2020-09-10 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-08 (8)/ 2020-09-11 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152092; Age (years): 60; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-07 (3)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152092; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-13 (9)/ 2020-08-14 (10)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS (ERYTHEMA)	2020-08-13 (9)/ 2020-08-20 (16)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-13 (9)/ 2020-08-20 (16)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152120; Age (years): 32; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-08 (5)/ 2020-09-12 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152134; Age (years): 55; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-18 (8)/ 2020-08-19 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152160; Age (years): 52; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-17 (3)/ 2020-09-18 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152177; Age (years): 31; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Immune system disorders/ Seasonal allergy/ EXACERBATION OF SEASONAL ALLERGIES	2020-09-16 (6)/ 2020-09-18 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152212; Age (years): 34; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-07 (25)/ 2020-09-08 (26)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152222; Age (years): 40; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-15 00:00 (1)/ 2020-08-20 00:00 (6)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152231; Age (years): 66; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-01 09:00 (1)/ 2020-10-01 19:00 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152232; Age (years): 46; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPING	2020-09-15 (2)/ 2020-09-15 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152232; Age (years): 46; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOLS	2020-09-15 (2)/ 2020-09-15 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-16 (3)/ 2020-09-21 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152238; Age (years): 41; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ PAIN- BILATERAL, WRIST	2020-09-15 (1)/ 2020-09-30 (16)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-19 (5)/ 2020-09-20 (6)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152238; Age (years): 41; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-22 (8)/ 2020-09-23 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 (9)/ 2020-09-26 (12)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152248; Age (years): 41; Sex: F; Race: WHITE							
Nervous system disorders/ Parosmia/ DISTURBANCE OF SMELL	2020-08-18 (4)/ 2020-08-18 (4)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-08-18 (4)/ 2020-08-22 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152248; Age (years): 41; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-19 (5)/ 2020-08-23 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-20 (6)/ 2020-08-22 (8)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
			1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-20 (6)/ 2020-08-22 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152248; Age (years): 41; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-22 (8)/ 2020-08-23 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-22 (8)/ 2020-08-27 (13)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-22 (8)/ 2020-09-23 (40)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-15 08:00 (31)/ 2020-10-27 (74)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152248; Age (years): 41; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ GENERALIZED BODY ACHES	2020-09-22 (8)/ 2020-09-23 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152266; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-22 (8)/ 2020-08-23 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-22 (8)/ 2020-08-23 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY LYMPHADENOPATHY	2020-08-22 (8)/ 2020-08-25 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152322; Age (years): 59; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-08-27 (8)/ 2020-09-05 (17)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Macule/ HYPERPIGMENTED MACULE LEFT DELTOID	2020-09-24 (8)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3152339; Age (years): 48; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-28 (8)/ 2020-09-29 (40)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152341; Age (years): 36; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-28 (8)/ 2020-09-05 (16)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152383; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-01 (9)/ 2020-09-02 (10)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152413; Age (years): 48; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-11-04 (9)/ 2020-11-06 (11)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152417; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-06 (8)/ 2020-10-07 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152430; Age (years): 25; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING LEFT SHOULDER PAIN	2020-10-04 (3)/ 2020-10-15 (14)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Neck pain/ WORSENING NECK PAIN	2020-10-04 (3)/ 2020-10-15 (14)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152446; Age (years): 50; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE	2020-10-14 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152447; Age (years): 34; Sex: M; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-06 21:00 (2)/ 2020-11-07 07:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152450; Age (years): 45; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-05 15:00 (2)/ 2020-11-09 20:00 (6)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152454; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-07 (3)/ 2020-11-07 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152456; Age (years): 43; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Axillary pain/ LEFT UNDERARM TENDERNESS	2020-10-16 (9)/ 2020-10-17 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-10-16 (9)/ 2020-10-17 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-16 (9)/ 2020-10-17 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152456; Age (years): 43; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-10-16 (9)/ 2020-10-17 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152464; Age (years): 56; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-10-19 (8)/ 2020-10-29 (18)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-19 (8)/ 2020-10-29 (18)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152464; Age (years): 56; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-10-19 (8)/ 2020-10-29 (18)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152496; Age (years): 37; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITIS	2020-10-21 (7)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-10-22 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152508; Age (years): 55; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE (LEFT DELTOID)	2020-10-28 (9)/ 2020-10-29 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (LEFT DELTOID)	2020-10-28 (9)/ 2020-10-30 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152515; Age (years): 33; Sex: M; Race: NOT REPORTED							
General disorders and administration site conditions/ Injection site induration/ INJECTION SITE HARDNESS	2020-10-22 18:00 (2)/ 2020-10-31 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152515; Age (years): 33; Sex: M; Race: NOT REPORTED							
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY LYMPHADENOPATHY	2020-10-27 (7)/ 2020-10-31 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152517; Age (years): 50; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-28 (8)/ 2020-10-30 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152531; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-10-29 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT ANTERIOR CERVICAL LYMPHADENOPATHY	2020-10-29 (8)/ 2020-11-02 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152531; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-10-29 (8)/ 2020-11-02 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152537; Age (years): 62; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-01 (11)/ 2020-11-01 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162011; Age (years): 70; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-26 09:00 (1)/ 2020-08-26 15:00 (1)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162021; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE LASTING BEYOND DAY 7	2020-08-26 07:00 (28)/ 2020-09-03 (37)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162026; Age (years): 73; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-27 07:00 (1)/ 2020-08-28 17:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162033; Age (years): 34; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE, MACULOPAPULAR	2020-07-30 (1)/ 2020-08-27 (29)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162033; Age (years): 34; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ URTICARIA AT INJECTION SITE	2020-08-07 (9)/ 2020-08-10 (12)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ PRURITUS AT INJECTION SITE	2020-08-27 (1)/ 2020-09-01 (6)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE AFTER DAY 7	2020-08-27 07:30 (28)/ 2020-09-07 (40)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162033; Age (years): 34; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ REDNESS AT INJECTION SITE AFTER DAY 7, MACULOPAPULAR AND URTICARIAL, RIGHT ARM	2020-08-27 07:30 (28)/ 2020-09-11 (44)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ ACUTE HEADACHE	2020-09-02 (7)/ 2020-09-08 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162042; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ DELAYED REDNESS AT INJECTION SITE, MACULAR AND NON-URTICARIAL	2020-09-02 (9)/ 2020-09-04 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162048; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS INJECTION SITE BEYOND DAY 7, MACULAR, NON-URTICARIAL	2020-08-03 (1)/ 2020-08-12 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Pruritus/ ALL-OVER-BODY PRURITUS	2020-08-03 20:00 (1)/ 2020-08-07 07:30 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE BEYOND DAY 7, MACULAR, NON-URTICARIAL	2020-08-31 (1)/ 2020-09-14 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162048; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE BEYOND DAY 7	2020-09-07 (8)/ 2020-09-14 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE BEYOND DAY 7	2020-09-07 (8)/ 2020-09-14 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162067; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ DELAYED INJECTION SITE REACTION (HARDNESS STARTING AFTER DAY 7)	2020-08-14 (9)/ 2020-08-17 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162067; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ DELAYED INJECTION SITE REACTION (REDNESS STARTING AFTER DAY 7), MACULAR, NON-URTICARIAL	2020-08-14 (9)/ 2020-08-17 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162069; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ DELAYED REACTION AT INJECTION SITE - REDNESS STARTING AFTER DAY 7, MACULAR AND URTICARIAL	2020-08-13 (8)/ 2020-08-22 (17)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162069; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ DELAYED REACTION AT INJECTION SITE - SWELLING STARTING AFTER DAY 7	2020-08-13 (8)/ 2020-08-22 (17)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site rash/ REDNESS AT INJECTION SITE AFTER DAY 7, MACULOPAPULAR AND URTICARIAL	2020-09-05 07:00 (1)/ 2020-09-14 07:00 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162069; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-05 21:30 (2)/ 2020-09-09 07:00 (5)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162071; Age (years): 76; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ DELAYED INJECTION SITE REACTION (REDNESS STARTING AFTER DAY 7), MACULAR, NON-URTICARIAL	2020-08-14 (9)/ 2020-08-24 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162071; Age (years): 76; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ DELAYED INJECTION SITE REACTION (SWELLING STARTING AFTER DAY 7)	2020-08-14 (9)/ 2020-08-24 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162086; Age (years): 55; Sex: F; Race: NOT REPORTED							
General disorders and administration site conditions/ Injection site rash/ DELAYED INJECTION SITE RASH, PAPULAR AND URTICARIAL	2020-08-25 (19)/ 2020-08-26 (20)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162096; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INJECTION SITE HARDNESS BEYOND DAY 7	2020-09-09 10:00 (1)/ 2020-09-20 (13)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITUS	2020-09-15 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162100; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE BEYOND DAY 7	2020-09-09 23:00 (1)/ 2020-09-17 08:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162104; Age (years): 31; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES LASTING BEYOND DAY 7	2020-08-15 (4)/ 2020-08-20 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES LASTING BEYOND DAY 7	2020-08-15 (4)/ 2020-08-20 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE BEYOND DAY 7	2020-09-09 18:00 (1)/ 2020-09-16 12:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162106; Age (years): 37; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ DELAYED INJECTION SITE REACTION (REDNESS STARTING DAY 8, NOT PRESENT DAYS 1-7), MACULAR, NON-URTICARIAL	2020-08-20 (9)/ 2020-08-22 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162117; Age (years): 26; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ REDNESS OF INJECTION SITE PAST DAY 7, MACULAR AND URTICARIAL	2020-08-14 (2)/ 2020-08-24 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-10 14:45 (1)/ 2020-09-13 14:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162118; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITUS	2020-09-14 22:30 (1)/ 2020-09-17 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site urticaria/ REDNESS AT INJECTION SITE BEYOND DAY 7, MACULAR, URTICARIAL	2020-09-14 22:30 (1)/ 2020-09-29 (16)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162122; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ DELAYED INJECTION SITE SWELLING	2020-09-24 (8)/ 2020-10-02 (16)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162122; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ DELAYED INJECTION SITE PAIN	2020-09-24 (8)/ 2020-10-10 (24)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162156; Age (years): 45; Sex: M; Race: WHITE							
Nervous system disorders/ Dysgeusia/ DYSGEUSIA	2020-09-17 14:15 (1)/ 2020-09-18 15:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162157; Age (years): 48; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-18 (1)/ 2020-09-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162168; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE AFTER DAY 7	2020-08-28 (8)/ 2020-08-29 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ GENERALIZED BODY ACHES AFTER DAY 7	2020-08-28 (8)/ 2020-08-29 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE AFTER DAY 7	2020-08-28 (8)/ 2020-08-30 (10)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162171; Age (years): 39; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Injection site macule/ REDNESS OF INJECTION SITE, MACULAR, NON-URTICARIAL	2020-08-28 (8)/ 2020-08-30 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162174; Age (years): 53; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ INJECTION SITE REDNESS AFTER DAY 7, MACULAR, NON-URTICARIAL	2020-08-22 08:00 (1)/ 2020-09-15 04:30 (25)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE AFTER DAY 7	2020-08-30 (10)/ 2020-09-02 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162174; Age (years): 53; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE BEYOND DAY 7	2020-09-18 06:30 (1)/ 2020-09-26 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162177; Age (years): 42; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE, DELAYED ONSET, MACULAR, NON URTICARIAL	2020-08-29 (9)/ 2020-09-04 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162181; Age (years): 77; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE LASTING PAST DAY 7	2020-09-01 (8)/ 2020-09-02 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162181; Age (years): 77; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE LASTING PAST DAY 7	2020-09-01 (8)/ 2020-09-03 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING BEYOND DAY 7	2020-09-22 (1)/ 2020-10-01 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162182; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE AFTER DAY 7, MACULAR, NON-URTICARIAL	2020-09-01 (8)/ 2020-09-12 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162182; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-23 (2)/ 2020-10-03 (12)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162183; Age (years): 82; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE AFTER DAY 7, MACULAR, NON-URTICARIAL	2020-09-01 (8)/ 2020-09-12 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162198; Age (years): 47; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE AFTER DAY 7	2020-09-04 (8)/ 2020-09-08 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162218; Age (years): 20; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-04 13:30 (1)/ 2020-09-12 13:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162220; Age (years): 38; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE STARTING AFTER DAY 7, MACULAR, NON-URTICARIAL	2020-09-12 (10)/ 2020-09-15 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE STARTING AFTER DAY 7	2020-09-12 (10)/ 2020-09-15 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162221; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Swelling/ LEFT UNDERARM SWELLING AFTER DAY 7	2020-09-12 (9)/ 2020-09-13 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162223; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE BEYOND DAY 7, MACULAR, NON URTICARIAL	2020-09-05 (2)/ 2020-09-12 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE BEYOND DAY 7	2020-09-05 (2)/ 2020-09-13 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162225; Age (years): 68; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE STARTING AFTER DAY 7, MACULAR, NON-URTICARIAL	2020-09-17 (10)/ 2020-09-22 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162227; Age (years): 40; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE BEYOND DAY 7	2020-10-13 (8)/ 2020-10-14 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162253; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE STARTING AFTER DAY 7	2020-10-06 (14)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE STARTING AFTER DAY 7	2020-10-06 (14)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162253; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ REDNESS AT INJECTION SITE STARTING AFTER DAY 7, MACULAR, URTICARIAL, LEFT ARM	2020-10-06 (14)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ ITCHINESS AT THE INJECTION SITE	2020-10-13 (21)/ 2020-10-20 (28)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162256; Age (years): 43; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Nausea/ INTERMITTENT NAUSEA	2020-09-29 (2)/ 2020-10-07 09:00 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162257; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE STARTING AFTER DAY 7	2020-10-09 (10)/ 2020-10-15 (16)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-10-09 (10)/ 2020-10-15 (16)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162265; Age (years): 40; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT LEG SORENESS	2020-10-13 (6)/ 2020-10-14 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162266; Age (years): 41; Sex: F; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY, IPSILATERAL	2020-11-12 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162278; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY, IPSILATERAL	2020-10-16 (4)/ 2020-10-31 (19)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162303; Age (years): 47; Sex: M; Race: ASIAN							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE IN MOUTH	2020-10-23 18:00 (1)/ 2020-10-24 08:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172008; Age (years): 58; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-08 10:00 (1)/ 2020-08-19 09:00 (12)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172017; Age (years): 58; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-09 12:11 (2)/ 2020-09-15 17:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ATHRALGIA (INTERMITTENT) GENERALIZED	2020-09-09 12:11 (2)/ 2020-09-20 08:00 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172017; Age (years): 58; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIA (INTERMITTENT)	2020-09-09 18:04 (2)/ 2020-09-20 08:00 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172050; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE LEFT DELTOID AREA ERYTHEMA (MACULOPAPULAR NON-URTICARIAL)	2020-08-19 (9)/ 2020-08-22 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172050; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INDURATION LEFT DELTOID AREA AT INJECTION SITE	2020-08-19 (9)/ 2020-08-22 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ MILD INJECTION SITE PAIN LEFT DELTOID AREA	2020-08-19 (9)/ 2020-08-22 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING LEFT DELTOID AREA	2020-08-19 (9)/ 2020-08-22 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172124; Age (years): 38; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenitis/ LEFT AXILLARY LYMPHADENITIS (IPSILATERAL)	2020-09-28 (18)/ 2020-10-01 (21)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172200; Age (years): 31; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED INTERMITTENT ARTHRALGIA	2020-09-17 20:00 (1)/ 2020-09-25 16:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTANT HEADACHE	2020-09-17 20:20 (1)/ 2020-09-25 16:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172200; Age (years): 31; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIA	2020-09-20 (4)/ 2020-09-25 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172221; Age (years): 44; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA INTERMITTENT GENERALIZED	2020-10-04 (17)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3172261; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM (DELTOID AREA) TENDERNESS	2020-08-21 15:00 (1)/ 2020-09-08 15:30 (19)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172261; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ LEFT ARM DELTOID AREA HARDNESS AT INJECTION SITE	2020-08-25 (5)/ 2020-09-08 (19)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172265; Age (years): 34; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ SKIN RASH (CONSISTENT WITH HIVES) (ARMS, LEGS, CHEST, AND BACK)	2020-08-22 23:00 (2)/ 2020-08-25 05:00 (4)	Yes/ No/ No	1	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172343; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ RIGHT DELTOID REDNESS ON THE INJECTION SITE (MACULOPAPULAR AND NON-URTICARIAL)	2020-09-03 (9)/ 2020-09-05 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172360; Age (years): 54; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Psoriasis/ PSORIASIS FLARE	2020-09-20 (25)/ 2020-11-17 (83)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3182086; Age (years): 28; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY LEFT SIDE	2020-08-31 20:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3182087; Age (years): 34; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ TENDINITIS OF RIGHT DELTOID	2020-09-07 (8)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3182133; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM PAIN	2020-09-10 (11)/ 2020-09-20 (21)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3182205; Age (years): 69; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Tinnitus/ TINNITUS	2020-08-15 (10)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192022; Age (years): 67; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH ON BILATERAL HANDS AND EXTREMITIES	2020-08-11 (10)/ 2020-08-17 (16)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192232; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (GENERALIZED)	2020-09-10 12:00 (1)/ 2020-09-22 08:00 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192233; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT THE INJECTION SITE	2020-08-21 (9)/ 2020-08-25 (13)	Yes/ No/ No	2	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192233; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT THE INJECTION SITE	2020-09-19 (2)/ 2020-09-21 (4)	Yes/ No/ No	2	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHES	2020-09-19 (2)/ 2020-09-21 (4)	Yes/ No/ No	2	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192355; Age (years): 38; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES - INTERMITTENT	2020-09-09 (17)/ 2020-10-12 (50)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192355; Age (years): 38; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE SORENESS	2020-09-09 (17)/ 2020-10-12 (50)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3192401; Age (years): 53; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ ARM PAIN	2020-09-19 (2)/ 2020-09-22 (5)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192497; Age (years): 37; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (1)/ 2020-09-25 (2)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 (1)/ 2020-09-26 (3)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192497; Age (years): 37; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-24 (1)/ 2020-09-26 (3)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-25 (2)/ 2020-09-25 (2)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-25 (2)/ 2020-09-25 (2)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-25 (2)/ 2020-09-27 (4)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192506; Age (years): 73; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL KNEE PAIN	2020-08-26 20:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NA	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3192521; Age (years): 33; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-25 (2)/ 2020-09-26 (3)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192611; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE	2020-09-08 (9)/ 2020-09-10 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192611; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INDURATION AT INJECTION SITE	2020-09-08 (9)/ 2020-09-10 (11)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-28 (1)/ 2020-09-30 (3)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-28 (1)/ 2020-09-30 (3)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192611; Age (years): 45; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-28 (1)/ 2020-09-30 (3)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202090; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS 3X4MM- PAPULAR, URTICARIAL	2020-08-18 (10)/ 2020-08-20 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-18 (10)/ 2020-08-20 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202090; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-08-18 (10)/ 2020-08-20 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3202091; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS, 9 DAYS POST VACCINATION	2020-08-09 (1)/ 2020-09-01 (24)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3202333; Age (years): 30; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-12 (50)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202355; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-05 (9)/ 2020-09-07 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212003; Age (years): 44; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-14 (12)/ 2020-08-15 (13)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212054; Age (years): 28; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY IPSILATERAL LYMPHADENOPATHY	2020-08-11 (7)/ 2020-08-14 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212089; Age (years): 41; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-14 (8)/ 2020-08-15 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA	2020-08-14 (8)/ 2020-08-18 (12)	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212090; Age (years): 54; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Hyperaesthesia teeth/ DENTIN SENSITIVITY	2020-09-05 (3)/ 2020-10-02 (30)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCERATIONS	2020-09-07 (5)/ Ongoing	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212091; Age (years): 43; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE AXILLARY LYMPHADENOPATHY, LEFT	2020-08-13 (7)/ 2020-08-16 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH	2020-08-15 (9)/ 2020-08-18 (12)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212100; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ BRUISED INJECTION SITE	2020-08-16 (7)/ 2020-08-21 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212105; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA	2020-08-14 (5)/ 2020-08-18 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212109; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ UPPER EXTREMITY PAIN IPSILATERAL TO INJECTION SITE	2020-08-13 (4)/ 2020-08-18 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212131; Age (years): 69; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Tooth discolouration/ TOOTH DISCOLORATION	2020-08-20 (10)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212142; Age (years): 41; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE SORENESS	2020-09-09 08:00 (28)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3212158; Age (years): 35; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY IPSILATERAL TO INJECTION SITE	2020-08-18 (6)/ 2020-08-21 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212178; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE LEFT AXILLARY LYMPHADENOPATHY	2020-08-15 11:00 (1)/ 2020-08-22 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212226; Age (years): 60; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 17:19 (1)/ 2020-09-30 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 17:19 (1)/ 2020-09-30 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212226; Age (years): 60; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-23 (7)/ 2020-09-30 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212242; Age (years): 42; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ MUSCLE ACHE AT INJECTION SITE	2020-09-26 (9)/ 2020-09-30 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212271; Age (years): 50; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA - BILATERAL HANDS	2020-08-21 (2)/ 2020-08-29 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212283; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-22 02:33 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-09-23 (3)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-23 (3)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Toothache/ TOOTH PAIN	2020-09-23 (3)/ 2020-11-06 (47)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212283; Age (years): 57; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 (5)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Sinusitis bacterial/ BACTERIAL SINUSITIS	2020-10-22 (32)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3212292; Age (years): 36; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-25 18:00 (1)/ 2020-08-31 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212294; Age (years): 53; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 (3)/ 2020-09-01 (8)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212316; Age (years): 47; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA OF THE STOMACH, BREASTS AND BILATERAL NECK.	2020-09-24 (3)/ 2020-09-26 (5)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Axillary pain/ SORENESS OF AXILLARY IPSILATERAL TO INJECTION SITE	2020-09-24 (3)/ 2020-09-30 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212326; Age (years): 46; Sex: F; Race: ASIAN							
Nervous system disorders/ Autonomic nervous system imbalance/ AUTONOMIC DYSFUNCTION	2020-10-18 (24)/ Ongoing	Yes/ Yes/ No	2	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212336; Age (years): 45; Sex: M; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-09-29 06:45 (1)/ 2020-09-30 (3)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212372; Age (years): 38; Sex: M; Race: WHITE							
Nervous system disorders/ Burning sensation/ "BURNING" ON BACK OF NECK AND EARS	2020-09-09 20:00 (1)/ 2020-09-09 22:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212394; Age (years): 62; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-12 07:30 (1)/ 2020-09-19 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-12 09:45 (1)/ 2020-09-18 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222039; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-05 00:00 (1)/ 2020-09-22 00:00 (18)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222054; Age (years): 54; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE/ARM REDNESS	2020-08-21 (14)/ 2020-08-26 (19)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222055; Age (years): 43; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-09 00:00 (1)/ 2020-08-10 00:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222137; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-14 06:00 (1)/ 2020-08-27 00:00 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHES	2020-09-13 00:00 (1)/ 2020-09-21 00:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-13 00:00 (1)/ 2020-09-24 00:00 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222213; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-26 (9)/ 2020-08-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222316; Age (years): 79; Sex: M; Race: WHITE							
Immune system disorders/ Type IV hypersensitivity reaction/ DELAYED TYPE-HYPERSENSITIVITY	2020-08-31 (8)/ 2020-09-04 (12)	Yes/ Yes/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222320; Age (years): 27; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING	2020-08-26 (2)/ 2020-09-01 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (1)/ 2020-10-04 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING	2020-09-25 (2)/ 2020-10-05 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222320; Age (years): 27; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-25 (2)/ 2020-10-09 (16)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-25 (2)/ 2020-10-10 (17)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222323; Age (years): 75; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	2020-10-01 (8)/ 2020-10-10 (17)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222334; Age (years): 57; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA - HANDS B/L AND BACK	2020-10-07 (13)/ 2020-10-29 (35)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222414; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-29 05:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-29 05:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222417; Age (years): 60; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-30 (3)/ 2020-10-07 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-30 (3)/ 2020-10-09 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (5)/ 2020-10-09 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-02 (5)/ 2020-10-11 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222417; Age (years): 60; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE	2020-10-03 (6)/ 2020-10-09 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222514; Age (years): 22; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-11 (2)/ 2020-10-18 (9)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222519; Age (years): 36; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 00:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222557; Age (years): 38; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Tinnitus/ TINNITUS	2020-10-12 (6)/ 2020-10-13 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222609; Age (years): 55; Sex: F; Race: OTHER: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY-CONTRALATERAL LYMPHADENOPATHY	2020-09-21 (6)/ 2020-09-29 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE	2020-11-03 00:00 (1)/ 2020-11-10 00:00 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222622; Age (years): 55; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-20 (1)/ 2020-11-10 (22)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222622; Age (years): 55; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ SITE INJECTION PAIN	2020-10-21 15:27 (1)/ 2020-10-30 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222643; Age (years): 25; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN LEFT HAND	2020-10-29 (2)/ 2020-11-01 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232017; Age (years): 32; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2020-09-13 (4)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232021; Age (years): 47; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING LOWER EXTREMETIES ARTHRALGIA	2020-08-25 (16)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING UPPER EXTREMITIES ARTHRALGIA	2020-08-25 (16)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING
Subject ID: US3232075; Age (years): 72; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 15:31 (2)/ 2020-09-23 13:24 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232086; Age (years): 43; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-04 (15)/ 2020-09-04 (15)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-04 (15)/ 2020-09-04 (15)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3232102; Age (years): 47; Sex: F; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-08-26 17:10 (2)/ 2020-09-22 11:30 (28)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232102; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site joint pain/ JOINT PAIN AT THE INJECTION SITE	2020-09-22 19:53 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3232105; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT SITE	2020-09-24 05:39 (1)/ 2020-09-27 06:36 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-24 05:39 (1)/ 2020-09-27 06:36 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232114; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-25 22:03 (2)/ 2020-09-27 23:03 (4)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232119; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-26 19:10 (2)/ 2020-09-27 18:50 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232134; Age (years): 44; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ CONTRALATERAL AXILLARY LYMPHADENOPATHY	2020-10-26 (29)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232135; Age (years): 48; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-30 05:00 (1)/ 2020-09-30 13:00 (2)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3232142; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ GENERALIZED PAIN	2020-10-05 23:00 (1)/ 2020-10-06 20:00 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232143; Age (years): 69; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ WHOLE BODY PAIN	2020-09-03 16:43 (2)/ 2020-09-04 13:00 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232178; Age (years): 58; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (1)/ 2020-09-19 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242016; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (10)/ 2020-10-28 (51)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242129; Age (years): 67; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-22 (7)/ 2020-09-27 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242131; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-23 (6)/ 2020-08-28 (11)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242131; Age (years): 57; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-08-23 (6)/ 2020-08-28 (11)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-08-23 (6)/ 2020-08-28 (11)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-23 (6)/ 2020-08-29 (12)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242167; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-08-29 (10)/ 2020-09-03 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-29 (10)/ 2020-09-03 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242192; Age (years): 87; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-25 12:25 (1)/ 2020-09-09 (17)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242198; Age (years): 70; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-08-28 (4)/ 2020-09-02 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-01 (8)/ 2020-09-01 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-01 (8)/ 2020-09-01 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-01 (8)/ 2020-09-01 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242203; Age (years): 32; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING, LEFT ARM	2020-09-01 (8)/ 2020-09-01 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-01 (8)/ 2020-09-01 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN, LEFT	2020-09-01 (8)/ 2020-09-01 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242203; Age (years): 32; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-01 (8)/ 2020-09-01 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN, LEFT ARM	2020-09-30 (8)/ 2020-09-30 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242237; Age (years): 69; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-03 (8)/ 2020-09-03 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242237; Age (years): 69; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-03 (8)/ 2020-09-03 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-03 (8)/ 2020-09-03 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 08:00 (1)/ 2020-10-05 (11)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242237; Age (years): 69; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-26 08:00 (1)/ 2020-10-05 (11)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-26 08:00 (1)/ 2020-10-05 (11)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242245; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-01 (8)/ 2020-10-01 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242262; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-01 17:39 (1)/ 2020-09-10 (10)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242283; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-06 22:15 (2)/ 2020-10-12 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-10 (6)/ 2020-10-12 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242292; Age (years): 20; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-03 21:00 (1)/ 2020-09-11 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242311; Age (years): 29; Sex: F; Race: ASIAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY, LEFT NECK	2020-09-12 (4)/ Ongoing	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242344; Age (years): 49; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site haematoma/ INJECTION SITE HEMATOMA	2020-09-16 17:40 (1)/ 2020-09-18 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-12 19:08 (1)/ 2020-10-20 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242357; Age (years): 28; Sex: M; Race: OTHER: (b) (6)							
Blood and lymphatic system disorders/ Lymph node pain/ UNDERARM GLAND TENDERNESS	2020-09-22 01:00 (1)/ 2020-09-30 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 01:00 (1)/ 2020-10-03 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING, LEFT, LYMPHADENOPATHY	2020-10-28 11:00 (1)/ Ongoing	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242359; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-28 (8)/ 2020-09-28 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242359; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN, LEFT ARM	2020-09-28 (8)/ 2020-09-29 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-24 (5)/ 2020-10-28 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-25 (6)/ 2020-10-27 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242359; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN, LEFT ARM	2020-10-26 (7)/ 2020-10-30 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242378; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-01 (8)/ 2020-10-01 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-01 (8)/ 2020-10-02 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242378; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-22 10:00 (1)/ 2020-10-29 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-22 10:00 (1)/ 2020-10-29 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242395; Age (years): 31; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-27 (2)/ 2020-11-03 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242417; Age (years): 68; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-09 (5)/ 2020-11-13 (9)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242417; Age (years): 68; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-09 (5)/ 2020-11-13 (9)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3252051; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Induration/ INDURATION	2020-08-07 (2)/ 2020-08-10 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3252069; Age (years): 64; Sex: M; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-06 (3)/ 2020-09-06 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252233; Age (years): 36; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE LEFT AXILLARY LYMPHADENOPATHY	2020-08-23 (6)/ 2020-09-05 (19)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3252248; Age (years): 38; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin burning sensation/ DERMATOLOGIC BURN SENSATION	2020-08-19 12:42 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT SUPRACLAVICULAR LYMPHADENOPATHY	2020-08-25 (7)/ 2020-08-27 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252255; Age (years): 31; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT SUPRACLAVICULAR LYMPHADENOPATHY	2020-08-24 (6)/ 2020-09-09 (22)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3252366; Age (years): 76; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-28 15:15 (1)/ 2020-08-28 15:20 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3262012; Age (years): 71; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-02 15:00 (2)/ 2020-09-02 16:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3262045; Age (years): 40; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE (LEFT ARM)	2020-08-29 (2)/ 2020-08-29 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3262046; Age (years): 19; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-02 (4)/ 2020-08-02 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3262090; Age (years): 42; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-10 (7)/ 2020-08-12 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3262137; Age (years): 32; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-08-08 (1)/ 2020-08-09 (2)	Yes/ No/ No		No	R/ R	DOSE NOT CHANGED/ NONE	
Subject ID: US3262181; Age (years): 36; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM SORENESS	2020-08-14 (3)/ 2020-08-15 (4)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3262187; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT ARM, NON-URTICARIAL	2020-08-28 (14)/ 2020-08-29 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3262211; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (2)/ 2020-09-24 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3262222; Age (years): 38; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 (2)/ 2020-09-22 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-22 05:30 (1)/ 2020-09-22 14:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-23 (3)/ 2020-09-24 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3262234; Age (years): 40; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-23 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3262235; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-23 (2)/ 2020-10-23 (32)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3262240; Age (years): 43; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE LEFT ARM	2020-08-30 19:00 (6)/ 2020-08-30 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3262240; Age (years): 43; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-28 (1)/ 2020-09-30 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-28 19:00 (1)/ 2020-09-30 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-28 19:00 (1)/ 2020-09-30 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272081; Age (years): 34; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-09 (2)/ 2020-09-10 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272081; Age (years): 34; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-09 (2)/ 2020-09-10 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 (2)/ 2020-09-11 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (GENERALIZED)	2020-09-09 00:00 (1)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272137; Age (years): 56; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (1)/ 2020-10-14 (27)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272204; Age (years): 71; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272204; Age (years): 71; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (GENERALIZED)	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282013; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-01 19:00 (2)/ 2020-09-07 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282013; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-01 20:00 (2)/ 2020-09-07 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-05 (6)/ 2020-09-07 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-05 (6)/ 2020-09-07 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282013; Age (years): 69; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-09-06 (7)/ 2020-09-07 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282047; Age (years): 85; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-12 18:00 (2)/ 2020-09-18 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282052; Age (years): 76; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-08-20 (7)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282052; Age (years): 76; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-08-20 (7)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-09 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3282058; Age (years): 66; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-12 (2)/ 2020-09-20 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282058; Age (years): 66; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-12 (2)/ 2020-09-20 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282063; Age (years): 43; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-15 20:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-15 20:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3282068; Age (years): 59; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 09:00 (1)/ 2020-09-29 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282068; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-22 18:00 (2)/ 2020-10-01 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292068; Age (years): 66; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-07 (3)/ 2020-09-07 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-07 (3)/ 2020-09-07 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292068; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-07 (3)/ 2020-09-07 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292074; Age (years): 31; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site irritation/ INJECTION SITE IRRITATION	2020-08-15 (8)/ 2020-08-17 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292090; Age (years): 24; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-06 10:54 (1)/ 2020-09-07 10:51 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292189; Age (years): 36; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenitis/ LEFT AXILLARY LYMPH NODE SWELLING	2020-08-17 (3)/ 2020-09-28 (45)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292241; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-20 (1)/ 2020-09-21 (33)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ OCCIPITAL HEADACHE	2020-08-20 (1)/ 2020-09-30 (42)	Yes/ No/ Yes	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN LYMPHNODES	2020-08-21 (2)/ 2020-10-27 (69)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292250; Age (years): 67; Sex: M; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-22 (6)/ 2020-09-22 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292276; Age (years): 39; Sex: M; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash/ RASH	2020-08-29 (9)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292279; Age (years): 51; Sex: F; Race: WHITE							
Nervous system disorders/ Somnolence/ MILD DROWSINESS THAT LAST 1 HOUR	2020-08-21 18:30 (1)/ 2020-08-21 19:30 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292284; Age (years): 71; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ L AXILLARY LYMPADENOPATHY	2020-08-23 (3)/ 2020-10-31 (72)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292284; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT ARM SORENESS	2020-09-25 (2)/ 2020-10-31 (38)	Yes/ No/ No	1	No	R/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292354; Age (years): 67; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-10 (15)/ 2020-09-24 (29)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-24 (1)/ 2020-10-01 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302027; Age (years): 66; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-16 (17)/ 2020-09-16 (17)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-16 (17)/ 2020-10-03 (34)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-16 (17)/ 2020-10-04 (35)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCULAR ACHES	2020-09-16 (17)/ 2020-10-07 (38)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302027; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE SHOOTING PAINS	2020-09-16 (17)/ 2020-10-08 (39)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Erectile dysfunction/ ERECTILE DYSFUNCTION	2020-09-16 (17)/ 2020-10-08 (39)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (17)/ 2020-10-11 (42)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCULAR WEAKNESS	2020-09-16 (17)/ 2020-10-11 (42)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312014; Age (years): 40; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED RAISED, URTICARIAL, ERYTHEMATOUS RASH (ON CHEST, STOMACH, PROXIMAL UPPER AND LOWER EXTREMITIES)	2020-09-08 (2)/ 2020-09-10 (4)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312017; Age (years): 57; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL UNDERARM GLAND SWELLING (LYMPHADENOPATHY) ON LEFT	2020-08-16 (7)/ 2020-08-18 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312030; Age (years): 78; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS (MACULAR NON-URTICARIAL) AT INJECTION SITE (LEFT ARM)	2020-09-09 (3)/ 2020-10-18 (42)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312043; Age (years): 20; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (2)/ 2020-09-21 (7)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312055; Age (years): 34; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT UNDERARM TENDERNESS (LYMPHADENOPATHY)	2020-09-16 (8)/ 2020-09-17 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312091; Age (years): 24; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-20 (7)/ 2020-09-22 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312092; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ MACULAR NON-UTICARIAL REDNESS AT INJECTION SITE	2020-09-11 (1)/ 2020-09-21 (11)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-11 (1)/ 2020-09-21 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312100; Age (years): 44; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-16 (3)/ 2020-09-17 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312109; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ LEFT INJECTION SITE RASH (NON-URTICARIAL)	2020-08-25 (9)/ 2020-08-29 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-14 (1)/ 2020-09-21 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312109; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE (MACULAR/NON-UTICARIAL)	2020-09-15 (2)/ 2020-09-22 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312120; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE (LEFT) MACULOPAPULAR NON-URTICARIAL RASH	2020-08-25 (8)/ 2020-08-28 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312147; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling/ RIGHT AXILLARY SWELLING IPSILATERAL TO VACCINATION	2020-08-26 (8)/ 2020-08-31 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT IPSALATERAL AXILLARY LYMPHADENOPATHY	2020-09-16 (1)/ 2020-09-18 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312154; Age (years): 82; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS (MACULAR/NON-UTICARIAL)	2020-09-17 (2)/ 2020-09-24 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312154; Age (years): 82; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-17 (2)/ 2020-09-24 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312157; Age (years): 21; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT IPSILATERAL GLAND SWELLING UNDERARM (LYMPHADENOPATHY)	2020-08-21 (3)/ 2020-08-27 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312178; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-18 (2)/ 2020-09-25 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312180; Age (years): 25; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenitis/ IPSILATERAL SWELLING UNDERARM GLAND	2020-08-25 (6)/ 2020-08-27 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-26 (7)/ 2020-08-27 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312186; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ LEFT MACULAR NON-URTICARIAL REDNESS AT INJECTION SITE	2020-09-17 (1)/ 2020-09-26 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312186; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-17 (1)/ 2020-09-26 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312188; Age (years): 78; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INDURATION AT INJECTION SITE	2020-08-28 (9)/ 2020-08-30 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE (LEFT ARM)	2020-08-28 (9)/ 2020-08-30 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312188; Age (years): 78; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ MACULAR URTICARIAL RASH AT INJECTION SITE (LEFT ARM)	2020-08-28 (9)/ 2020-09-26 (38)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312190; Age (years): 47; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT 1 CENTIMETER IPSILATERAL AXILLARY LYMPHADENOPATHY	2020-09-17 11:57 (28)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-09-20 (4)/ 2020-09-26 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312190; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 (6)/ 2020-09-27 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312191; Age (years): 34; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (1)/ 2020-09-24 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-23 (7)/ 2020-09-24 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 (7)/ 2020-09-24 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312213; Age (years): 70; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-26 (6)/ 2020-08-28 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312219; Age (years): 67; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ NON-UTICARIAL MACULAR RASH AT INJECTION SITE (RIGHT ARM)	2020-08-28 (8)/ 2020-08-31 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312221; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ URTICARIAL RASH AT INJECTION SITE (LEFT ARM)	2020-08-28 (8)/ 2020-09-13 (24)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312234; Age (years): 58; Sex: M; Race: UNKNOWN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-22 (2)/ 2020-09-23 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312254; Age (years): 52; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-26 (6)/ 2020-09-30 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312266; Age (years): 51; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-08-28 (4)/ 2020-09-12 (19)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312266; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-29 (5)/ 2020-09-15 (22)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312279; Age (years): 26; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-20 (27)/ 2020-09-20 (27)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-21 (28)/ 2020-09-21 (28)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312287; Age (years): 26; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-29 (7)/ 2020-10-03 (11)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312299; Age (years): 39; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-01 (9)/ 2020-10-05 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312300; Age (years): 31; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY (LEFT IPSILATERAL UNDERARM GLAND SWELLING)	2020-09-24 08:00 (1)/ 2020-09-30 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312350; Age (years): 20; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH LEFT ARM	2020-09-03 (8)/ 2020-09-06 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312367; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE (LEFT) MACULAR NON-UTICAIRAL RASH	2020-09-04 (8)/ 2020-09-07 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH	2020-09-28 (4)/ 2020-10-04 (10)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312380; Age (years): 59; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA (NON-URTICARIAL)	2020-09-06 (10)/ 2020-09-06 (10)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312384; Age (years): 41; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-01 (7)/ 2020-10-03 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312411; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH	2020-10-01 (4)/ 2020-10-17 (20)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312428; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ LEFT ARM URTICARIAL INJECTION SITE RASH	2020-09-09 (9)/ 2020-09-09 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312428; Age (years): 40; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-18 (18)/ 2020-09-23 (23)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 (19)/ 2020-09-20 (20)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-19 (19)/ 2020-09-23 (23)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-19 (19)/ 2020-09-23 (23)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312428; Age (years): 40; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (24)/ 2020-09-24 (24)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-24 (24)/ 2020-09-24 (24)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312432; Age (years): 79; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ INJECTION SITE RASH (MACULAR URTICARIAL)	2020-09-09 (9)/ 2020-09-12 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312448; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site rash/ PRURITIC INJECTION SITE RASH	2020-09-09 (8)/ 2020-09-15 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312463; Age (years): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL GLAND SWELLING UNDERARM (LYMPHADENOPATHY)	2020-09-07 (6)/ 2020-09-14 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-11 (10)/ 2020-09-16 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312463; Age (years): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE ITCHING	2020-09-14 (13)/ 2020-09-16 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312500; Age (years): 53; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-10-04 (3)/ 2020-10-07 (6)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312549; Age (years): 21; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-18 (11)/ 2020-09-19 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312569; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ LEFT ARM INJECTION SITE SWELLING	2020-09-10 (2)/ 2020-10-15 (37)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312585; Age (years): 46; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL UNDERARM TENDERNESS (LYMPHADENOPATHY)	2020-09-16 (8)/ 2020-09-19 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-16 (8)/ 2020-09-20 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312593; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (7)/ 2020-09-17 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-16 (7)/ 2020-09-17 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenitis/ IPSILATERAL UNDERARM GLAND SWELLING	2020-09-16 (7)/ 2020-09-23 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenitis/ IPSILATERAL UNDERARM GLAND SWELLING	2020-10-08 (1)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312598; Age (years): 53; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ MACULAR NON-URTICARIAL REDNESS AT INJECTION SITE	2020-09-10 17:30 (1)/ 2020-10-24 (45)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-17 (8)/ 2020-09-28 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312624; Age (years): 27; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT UNDERARM GLAND SWELLING (LYMPHADENOPATHY)	2020-09-15 (5)/ 2020-09-22 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312624; Age (years): 27; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT UNDERARM GLAND TENDERNESS (LYMPHADENOPATHY)	2020-09-15 (5)/ 2020-09-22 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312634; Age (years): 36; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ IPSILATERAL INJECTION SITE MACULAR URTICARIAL RASH	2020-09-18 (8)/ 2020-09-23 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312639; Age (years): 37; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE(LEFT ARM) MACULOPAPULAR KERATINIZED RASH	2020-09-21 (11)/ 2020-09-27 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322029; Age (years): 29; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN - LEFT UPPER ARM	2020-08-18 (1)/ 2020-09-18 (32)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3322057; Age (years): 58; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-18 (2)/ 2020-09-24 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-02 (47)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322167; Age (years): 52; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PERSISTENT SHOULDER PAIN ON SAME ARM AS INJECTION SITE (LEFT)	2020-09-01 18:30 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322219; Age (years): 62; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ HIVES	2020-09-04 (2)/ 2020-09-06 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322308; Age (years): 28; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ DELAYED SITE INJECTION REACTION (RASH) OF LEFT UPPER EXTREMITY	2020-09-20 (9)/ 2020-09-22 (11)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322324; Age (years): 29; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-30 (23)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-10-30 (23)/ 2020-10-30 (23)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-30 (23)/ 2020-10-31 (24)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-30 (23)/ 2020-11-01 (25)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322324; Age (years): 29; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGHING	2020-10-31 (24)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-31 (24)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322329; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling face/ FACIAL SWELLING	2020-10-17 (3)/ 2020-10-22 (8)	Yes/ Yes/ No	3	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322344; Age (years): 39; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINTS PAIN	2020-10-13 (2)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-13 (2)/ 2020-10-13 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332006; Age (years): 35; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Asthma/ WORSENING OF ASTHMA	2020-08-31 20:00 (1)/ 2020-09-06 08:00 (6)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332015; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-03 20:00 (1)/ 2020-09-11 14:00 (9)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332023; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-07 08:00 (1)/ 2020-08-14 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-04 08:00 (1)/ 2020-09-11 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332051; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-12 14:00 (2)/ 2020-09-18 23:00 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332059; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-18 10:00 (25)/ 2020-09-29 09:00 (36)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3332061; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Vaccination site lymphadenopathy/ AXILLARY LYMPHADENOPATHY IPSILATERAL-SAME SIDE OF VACCINATION SITE	2020-08-31 (7)/ 2020-09-02 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3332074; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-08 (8)/ 2020-09-11 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332074; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-10 (10)/ 2020-09-11 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3332081; Age (years): 64; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 19:20 (1)/ 2020-09-19 20:00 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3332099; Age (years): 51; Sex: F; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-13 17:50 (1)/ 2020-10-21 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332100; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHY BUMP AT INJECTION SITE	2020-11-18 (6)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site swelling/ RED BUMP AT INJECTION SITE	2020-11-18 (6)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342028; Age (years): 54; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-08 21:00 (1)/ 2020-09-17 09:00 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342028; Age (years): 54; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-08 21:00 (1)/ 2020-09-17 09:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342054; Age (years): 41; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ REACTIVE LYMPHADENOPATHY - BILATERAL AXILLARY	2020-09-19 (4)/ 2020-09-25 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ REACTIVE LYMPHADENOPATHY BILATERAL TRAPEZIUS NODE	2020-09-20 (5)/ 2020-09-22 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ REACTIVE LYMPHADENOPATHY OF RIGHT ACHILLES	2020-09-21 (6)/ 2020-09-24 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342057; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ LEFT AXILLARY MYALGIA AT THE INJECTION SITE.	2020-08-21 (9)/ 2020-08-25 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY AT THE INJECTION SITE	2020-08-21 (9)/ 2020-08-26 (14)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	2020-09-10 19:00 (1)/ 2020-09-18 16:30 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342057; Age (years): 62; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ MILD REACTIVE LYMPHADENOPATHY LEFT AXILLA IPSILATERAL	2020-09-10 19:00 (1)/ 2020-09-22 13:00 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342063; Age (years): 46; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Malaise/ WORSENING OF GENERALIZED MALAISE	2020-09-21 (8)/ 2020-10-02 (19)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342065; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ SYSTEMIC EVENT: FATIGUE	2020-09-21 (4)/ 2020-09-28 (11)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342071; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN RIGHT ARM	2020-09-17 17:00 (1)/ 2020-09-28 23:00 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342072; Age (years): 33; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site papule/ IRRITATION AT INJECTION SITE (L) ARM PAPULAR AND NON-URTICARIAL	2020-08-20 (7)/ 2020-08-23 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA (L) ARM	2020-08-20 (7)/ 2020-08-24 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342074; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ GENERALIZED FATIGUE	2020-09-15 17:00 (1)/ 2020-09-23 08:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural headache/ HEADACHE (POST-VACCINATION #2)	2020-09-15 17:00 (1)/ 2020-09-24 08:00 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342120; Age (years): 40; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Polyarthritis/ SUBACUTE SYMMETRICAL POLYARTHRITIS	2020-09-30 (10)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342145; Age (years): 21; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 12:00 (1)/ 2020-09-12 (18)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA IN KNEE	2020-09-01 (7)/ 2020-09-06 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA IN LOWER BACK	2020-09-01 (7)/ 2020-09-06 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342181; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT ARM	2020-09-06 (4)/ 2020-09-11 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Vaccination complication/ GENERALIZED ARTHRALGIA MULTIPLE JOINTS POST VACCINATION	2020-09-06 (4)/ 2020-09-11 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE LEFT ARM	2020-09-06 (4)/ 2020-09-12 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342191; Age (years): 43; Sex: M; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-10-13 09:00 (1)/ 2020-10-20 12:46 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342205; Age (years): 29; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Peripheral sensory neuropathy/ SENSORY NEUROPATHY LEFT ARM	2020-09-09 12:00 (2)/ 2020-09-14 08:00 (6)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342228; Age (years): 67; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA SECONDARY TO INTRAMUSCULAR INJECTION	2020-10-19 (5)/ 2020-10-22 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342234; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-15 19:00 (2)/ 2020-10-22 09:00 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 19:00 (2)/ 2020-10-22 09:00 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-10-15 19:00 (2)/ 2020-10-22 09:00 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342234; Age (years): 68; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-15 19:00 (2)/ 2020-10-22 09:00 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 19:00 (2)/ 2020-10-22 09:00 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342277; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ LEFT DELTOID MYALGIA SECONDARY TO IM INJECTION	2020-10-01 (9)/ 2020-10-02 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342296; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ ACUTE VIRAL ILLNESS	2020-10-18 (20)/ 2020-10-24 (26)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342347; Age (years): 25; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-18 09:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3342357; Age (years): 46; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE (POST 7-DAY E-DIARY)	2020-10-19 (7)/ 2020-10-21 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342361; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN RIGHT ARM	2020-10-14 17:00 (1)/ 2020-10-21 17:30 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352046; Age (years): 61; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-29 (22)/ 2020-10-09 (32)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352067; Age (years): 28; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (LEFT UPPER DELTOID)	2020-08-13 (1)/ 2020-08-29 (17)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352083; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT THE INJECTION SITE (LEFT UPPER DELTOID) NON-URTICARIAL	2020-08-17 (5)/ 2020-08-24 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-08 12:11 (1)/ 2020-09-19 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-09 (2)/ 2020-09-19 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352083; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENREALIZED MUSCLE ACHES	2020-09-10 (3)/ 2020-09-19 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352087; Age (years): 46; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-10 (1)/ 2020-10-06 (27)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352089; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-18 (6)/ 2020-08-21 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352110; Age (years): 49; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-18 13:49 (1)/ Ongoing	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352170; Age (years): 31; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-17 03:00 (28)/ 2020-09-20 08:00 (31)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352263; Age (years): 66; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ UNDER ARM TENDERNESS AT INJECTION SITE	2020-09-14 (21)/ 2020-09-17 (24)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Axillary pain/ LEFT UNDERARM TENDERNESS (INJECTION ARM)	2020-09-26 (5)/ 2020-09-30 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352287; Age (years): 23; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-22 (1)/ 2020-09-29 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352288; Age (years): 54; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 (1)/ 2020-09-30 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352338; Age (years): 48; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-08 20:00 (1)/ 2020-10-19 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-15 (8)/ 2020-10-18 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352476; Age (years): 54; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT UNDERARM GLAND SWELLING	2020-10-05 (7)/ 2020-10-19 (21)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenitis/ UNDERARN GLAND SWELLING	2020-10-28 00:00 (1)/ 2020-11-04 00:00 (8)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352484; Age (years): 48; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-09 (11)/ 2020-10-10 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352519; Age (years): 65; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-11-05 10:35 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362002; Age (years): 46; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-02 (3)/ 2020-08-02 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-02 (3)/ 2020-08-02 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362023; Age (years): 55; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Swollen tongue/ TONGUE SWELLING - POST INJECTION ALLERGIC REACTION	2020-08-03 16:20 (1)/ 2020-08-03 18:20 (1)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362051; Age (years): 34; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-10 (6)/ 2020-08-17 (13)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362057; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ Injection site cellulitis/ (INJECTION SITE) EOSINOPHILIC CELLULITIS, LEFT UPPER ARM	2020-08-13 (8)/ 2020-08-17 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362059; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site reaction/ SPORADIC MUSCLE SPASMS AT INJECTION SITE	2020-09-16 (13)/ 2020-09-17 (14)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362097; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ INJECTION SITE RASH RIGHT AXILLA(URTICARIAL)	2020-08-19 (10)/ 2020-08-28 (19)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362097; Age (years): 53; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Diabetes mellitus/ WORSENING DIABETES MELLITUS	2020-09-08 20:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362116; Age (years): 56; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-19 04:30 (1)/ 2020-09-20 10:00 (2)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIAS	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362116; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ WORSENING OF CHRONIC NECK PAIN	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362148; Age (years): 21; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 (3)/ 2020-10-06 (14)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362160; Age (years): 22; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL LEFT SUPRACLAVICULAR LYMPH NODE SWELLING	2020-08-22 (8)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3362204; Age (years): 57; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-30 (11)/ 2020-08-31 (12)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362308; Age (years): 61; Sex: M; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash/ LEFT ARM RASH	2020-10-19 (12)/ 2020-10-24 (17)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372012; Age (years): 58; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-02 (3)/ 2020-09-03 (4)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372047; Age (years): 50; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-09 (2)/ 2020-09-09 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-20 (13)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-20 (13)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-23 (16)/ 2020-09-24 (17)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372049; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-21 (19)/ 2020-09-24 (22)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372056; Age (years): 77; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-10 (2)/ 2020-09-10 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372065; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 (1)/ 2020-09-16 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372070; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-11 19:53 (2)/ 2020-08-18 19:00 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372070; Age (years): 65; Sex: F; Race: WHITE							
Psychiatric disorders/ Sleep disorder/ SLEEP DISTURBANCE	2020-09-11 (1)/ 2020-09-12 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372074; Age (years): 79; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ DIAPHORESIS	2020-09-16 (2)/ 2020-09-16 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-26 (12)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ INCREASED NASAL MUCUS	2020-09-26 (12)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372096; Age (years): 69; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 (14)/ 2020-09-22 (14)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372109; Age (years): 60; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-11 (2)/ 2020-09-18 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372188; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE RIGHT ARM	2020-09-24 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372205; Age (years): 68; Sex: F; Race: WHITE							
Nervous system disorders/ Sinus headache/ SINUS HEADACHE	2020-09-20 (3)/ 2020-09-20 (3)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372210; Age (years): 69; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS	2020-09-20 (31)/ 2020-09-23 (34)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372217; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INDURATION - INJECTION SITE (LEFT DELTOID)	2020-09-26 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3372221; Age (years): 30; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-24 14:37 (1)/ 2020-08-31 11:59 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372221; Age (years): 30; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Ecchymosis/ ECCHYMOSIS LEFT ARM	2020-08-28 (5)/ 2020-09-01 (9)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-21 (1)/ 2020-09-29 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-23 (3)/ 2020-09-29 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372227; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT THE INJECTION SITE-MACULAR-NON-URTICARIAL	2020-09-25 (3)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372235; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 (4)/ 2020-09-29 (8)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 (5)/ 2020-09-27 (6)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372239; Age (years): 58; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	2020-08-26 00:00 (1)/ 2020-08-29 00:00 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-08-27 (3)/ 2020-08-30 (6)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372241; Age (years): 27; Sex: F; Race: ASIAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-26 (33)/ 2020-09-26 (33)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372254; Age (years): 48; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	2020-09-25 (2)/ 2020-09-25 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372273; Age (years): 66; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHES THAT EXCEED 7 DAY POST DOSE	2020-09-25 (1)/ 2020-10-04 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES EXCEEDING 7 DAY POST DOSE	2020-09-25 (1)/ 2020-10-05 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372281; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Conjunctivitis/ CONJUNCTIVITIS RIGHT EYE	2020-08-31 (4)/ 2020-09-04 (8)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372315; Age (years): 69; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-10-06 (6)/ 2020-10-06 (6)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372334; Age (years): 73; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHES	2020-09-17 (15)/ 2020-09-23 (21)	Yes/ No/ No	1	No	R/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372376; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ Clostridium difficile infection/ INFECTION FOR CLOSTRIDIUM DIFFICILE TOXIN A AND B	2020-09-25 (1)/ 2020-11-05 (42)	Yes/ No/ No	1	No	R/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372416; Age (years): 73; Sex: F; Race: ASIAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 18:00 (1)/ 2020-10-21 15:00 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-21 12:37 (2)/ 2020-10-21 12:52 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372421; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Conjunctivitis/ CONJUNCTIVITIS RIGHT EYE	2020-11-06 (26)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-06 (26)/ 2020-11-13 (33)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372445; Age (years): 76; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY-AXILLARY, IPSILATERAL SAME SIDE OF VACCINATION SITE	2020-09-25 (4)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372447; Age (years): 46; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-05 (14)/ 2020-10-08 (17)	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3382015; Age (years): 33; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ L ARM SORENESS AT INJECTION SITE	2020-08-28 (18)/ 2020-08-30 (20)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3382024; Age (years): 73; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY	2020-08-13 20:00 (1)/ 2020-09-16 20:00 (35)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382067; Age (years): 43; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-25 (8)/ 2020-08-28 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3382080; Age (years): 45; Sex: M; Race: WHITE							
Vascular disorders/ Flushing/ FLUSH	2020-09-02 17:05 (14)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382082; Age (years): 35; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal discomfort/ STOMACH UPSET: DECREASED BOWEL MOVEMENT AND MODERATE PAIN	2020-08-26 (7)/ 2020-08-27 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3382134; Age (years): 33; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-30 (3)/ 2020-08-30 (3)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382134; Age (years): 33; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-31 (4)/ 2020-09-02 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3382140; Age (years): 50; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 00:00 (7)/ 2020-10-10 00:00 (12)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382147; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT THE INJECTION SITE	2020-10-03 (6)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382153; Age (years): 66; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-10 (12)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382168; Age (years): 25; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ RASH-ITCHY, NEAR INJECTION SITE, UNDER LEFT ARM AND LEFT BREAST AREA	2020-10-09 (10)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382175; Age (years): 60; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-04 (3)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382227; Age (years): 42; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-22 (14)/ 2020-09-22 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-23 (15)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382267; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ RASH OVER THE INJECTION SITE	2020-09-25 (14)/ 2020-09-26 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382267; Age (years): 49; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ GENERALIZED RASH	2020-10-13 (2)/ Ongoing	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3382282; Age (years): 50; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Malaise/ GENERAL MALAISE	2020-09-18 (4)/ 2020-09-19 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3382284; Age (years): 45; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-23 (8)/ 2020-09-25 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3402101; Age (years): 30; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	2020-08-06 (8)/ 2020-08-06 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402271; Age (years): 52; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT DELTOID	2020-09-03 12:00 (28)/ 2020-09-13 12:00 (38)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-09-04 (2)/ 2020-09-28 (26)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE	2020-09-04 00:00 (1)/ 2020-09-13 00:00 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402271; Age (years): 52; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN - MILD	2020-09-04 00:00 (1)/ 2020-09-13 00:00 (10)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-04 00:00 (1)/ 2020-09-13 00:00 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-04 12:00 (1)/ 2020-09-19 12:00 (16)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402319; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTED LEFT FOOT	2020-10-09 (29)/ 2020-10-21 (41)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402353; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-11 23:12 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3412129; Age (years): 37; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-12 (8)/ 2020-08-12 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422023; Age (years): 45; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash maculo-papular/ NON-URTICARIAL MACULOPAPULAR RASH ON CHEST	2020-09-18 (4)/ 2020-09-20 (6)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422125; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 (6)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3422127; Age (years): 40; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Skin and subcutaneous tissue disorders/ Rash maculo-papular/ NONURTICARIAL MACULOPAPULAR RASH AT L DELTOID	2020-09-26 (3)/ 2020-10-02 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422132; Age (years): 52; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIAS	2020-10-02 (8)/ 2020-10-07 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422142; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ URTICARIAL REDNESS AT L DELTOID INJECTION SITE 13 DAYS POST VACCINE	2020-09-09 (13)/ 2020-09-23 (27)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site urticaria/ URTICARIAL REDNESS AT L DELTOID INJECTION SITE	2020-09-26 14:00 (2)/ 2020-10-07 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422148; Age (years): 47; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-29 14:51 (2)/ 2020-10-07 15:27 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422148; Age (years): 47; Sex: F; Race: ASIAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 14:51 (2)/ 2020-10-07 15:27 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422151; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-29 14:00 (2)/ 2020-10-07 08:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-29 14:00 (2)/ 2020-10-07 08:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-04 (7)/ 2020-10-07 (10)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422187; Age (years): 25; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site induration/ INDURATION AT INJECTION SITE 9 DAYS POST VACCINE	2020-09-10 (9)/ 2020-09-16 (15)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site rash/ NON-URTICARIA MACULOPAPULAR AT INJECTION SITE 9 DAYS POST VACCINE	2020-09-10 (9)/ 2020-09-16 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422202; Age (years): 27; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash maculo-papular/ NON-URTICARIA MACULOPAPULAR OF LEFT DELTOID 9 DAYS POST VACCINATION	2020-09-11 (9)/ 2020-09-17 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422259; Age (years): 23; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES, GENERALIZED	2020-10-09 02:00 (1)/ 2020-10-17 10:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422274; Age (years): 42; Sex: F; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE MYALGIAS	2020-10-17 12:00 (2)/ 2020-11-05 08:00 (20)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432004; Age (years): 59; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-03 (1)/ 2020-08-05 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432016; Age (years): 76; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-03 00:00 (1)/ 2020-09-04 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432022; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-02 20:00 (1)/ 2020-09-03 22:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432043; Age (years): 30; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ RIGHT DELTOID INJECTION SITE PAIN	2020-09-12 (10)/ 2020-09-20 (18)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432057; Age (years): 28; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPH NODE (1/2 CM)	2020-09-04 (1)/ 2020-10-02 (29)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432060; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-08-09 (3)/ 2020-08-23 (17)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432064; Age (years): 25; Sex: F; Race: ASIAN							
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	2020-09-09 06:30 (1)/ 2020-09-09 10:40 (2)	Yes/ Yes/ No	4	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432066; Age (years): 64; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Swelling/ UNDERARM GLAND SWELLING (R)	2020-09-08 (4)/ 2020-09-21 (17)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432077; Age (years): 28; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Reactogenicity event/ REACTOGENICITY SYNDROME (CHILLS AND JOINT ACHES)	2020-08-11 (2)/ 2020-08-12 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432091; Age (years): 56; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-08-12 (2)/ 2020-08-12 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ SWELLING SUPRACLAVICULAR LYMPHNODE	2020-09-08 (1)/ 2020-10-20 (43)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432094; Age (years): 76; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL LYMPHADENOPATHY (RIGHT POSTERIOR CERVICAL CHAIN, RIGHT POSTERIOR MANDIBULAR, RIGHT SUPRACLAVICULAR)	2020-09-10 (1)/ 2020-10-08 (29)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432102; Age (years): 35; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-12 (2)/ 2020-08-19 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-22 (12)/ 2020-08-24 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432118; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Disturbance in attention/ LACK OF CONCENTRATION	2020-08-13 11:00 (1)/ 2020-08-13 21:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC B/P	2020-09-14 (1)/ 2020-09-15 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432124; Age (years): 24; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ ENLARGED LYMPH NODE (LEFT ARM PIT)	2020-08-17 (5)/ 2020-09-12 (31)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432125; Age (years): 49; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-08-21 (9)/	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITIS	2020-09-19 (5)/ 2020-09-23 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432132; Age (years): 38; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-09-11 (2)/ 2020-09-12 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432156; Age (years): 37; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 (6)/ 2020-09-22 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432158; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-12 20:00 (1)/ 2020-09-14 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432188; Age (years): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site erythema/ LATE ONSET INJECTION SITE REACTION (REDNESS)	2020-08-28 (11)/ 2020-09-10 (24)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432201; Age (years): 48; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA (LEFT UPPER ARM FOR VACCINE 1, RIGHT UPPER ARM FOR VACCINE 2)	2020-08-19 20:00 (1)/ 2020-09-29 (42)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432203; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS (100MM DAY 2; 80MM DAY 3)	2020-09-17 (2)/ 2020-09-18 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432219; Age (years): 42; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE (REACTOGENICITY)	2020-08-23 (4)/ 2020-08-26 (7)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432222; Age (years): 34; Sex: M; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ L SHOULDER PAIN	2020-08-20 19:30 (1)/ 2020-09-01 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432223; Age (years): 73; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-16 (1)/ 2020-09-16 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432225; Age (years): 20; Sex: M; Race: NOT REPORTED							
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 19:00 (1)/ 2020-09-23 21:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432236; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS (INJECTION SITE)	2020-09-19 09:00 (1)/ 2020-09-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432236; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING (INJECTION SITE)	2020-09-19 09:00 (1)/ 2020-09-26 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432240; Age (years): 69; Sex: M; Race: WHITE							
Vascular disorders/ Flushing/ FACIAL FLUSHING	2020-08-22 14:00 (1)/ 2020-08-22 23:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432288; Age (years): 70; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-29 08:00 (1)/ 2020-09-29 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432288; Age (years): 70; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-29 08:00 (1)/ 2020-09-29 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-29 08:00 (1)/ 2020-09-29 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES/BODY ACHES	2020-09-29 08:00 (1)/ 2020-09-29 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432293; Age (years): 38; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-24 10:00 (1)/ 2020-09-24 10:15 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432317; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-26 (3)/ 2020-09-26 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432318; Age (years): 49; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-15 09:00 (1)/ 2020-09-22 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432322; Age (years): 72; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-09-25 (2)/ 2020-09-26 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432348; Age (years): 66; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 (2)/ 2020-09-17 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432348; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITIS	2020-09-19 (4)/ 2020-10-11 (26)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-20 (5)/ 2020-09-20 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-22 (7)/ 2020-09-24 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 16:00 (2)/ 2020-10-22 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432349; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 (2)/ 2020-10-03 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-26 (2)/ 2020-10-03 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-26 (2)/ 2020-10-03 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432361; Age (years): 39; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ LATE-ONSET INJECTION SITE REACTION (REDNESS AND SWELLING) ON RIGHT DELTOID	2020-09-05 (8)/ 2020-09-08 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432364; Age (years): 73; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-28 16:01 (1)/ 2020-10-05 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-28 16:01 (1)/ 2020-10-12 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432372; Age (years): 66; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT CERVICAL LYMPHADENOPATHY IPSILATERAL TO VACCINATION	2020-09-28 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432377; Age (years): 21; Sex: M; Race: ASIAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING	2020-09-07 (7)/ 2020-09-08 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432381; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 (2)/ 2020-10-03 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432381; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-03 (2)/ 2020-10-03 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-03 (2)/ 2020-10-03 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-03 (2)/ 2020-10-03 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432389; Age (years): 92; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 (2)/ 2020-09-30 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432411; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN (RIGHT ARM)	2020-09-03 22:42 (1)/ 2020-09-09 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Axillary pain/ UNDERARM TENDERNESS (LEFT)	2020-10-07 (7)/ 2020-10-08 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432419; Age (years): 67; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-03 (3)/ 2020-10-03 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432448; Age (years): 41; Sex: M; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-10-06 15:35 (1)/ 2020-10-13 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-08 (4)/ 2020-10-08 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-08 (4)/ 2020-10-08 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432451; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	2020-09-12 (8)/ 2020-09-15 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432459; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site reaction/ LATE-ONSET INJECTION SITE REACTION	2020-09-21 (14)/ 2020-09-24 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432465; Age (years): 65; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH	2020-10-22 (17)/ 2020-10-22 (17)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH	2020-10-26 (21)/ 2020-10-26 (21)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432469; Age (years): 19; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHES	2020-09-13 (5)/ 2020-09-13 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432471; Age (years): 40; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-09 10:30 (1)/ 2020-10-02 (24)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432474; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-19 (10)/ 2020-10-24 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432479; Age (years): 29; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-10-13 (6)/ 2020-10-15 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 (8)/ 2020-10-16 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432490; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-08 21:00 (1)/ 2020-10-09 21:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432500; Age (years): 66; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-23 (10)/ 2020-09-24 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432512; Age (years): 66; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS (L DELTOID)	2020-10-22 (4)/ 2020-10-24 (6)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432513; Age (years): 59; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-17 09:00 (1)/ 2020-09-25 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432523; Age (years): 50; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site reaction/ LATE ONSET INJECTION SITE REACTION	2020-09-25 (8)/ 2020-09-30 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432541; Age (years): 66; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ CERVICAL LYMPHADENOPATHY	2020-10-23 (4)/ 2020-10-24 (5)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432545; Age (years): 57; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	2020-10-19 23:55 (1)/ 2020-10-24 (6)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432577; Age (years): 28; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pruritus/ PRURITIS (INJECTION SITE)	2020-11-05 (4)/ 2020-11-07 (6)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432597; Age (years): 72; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-05 19:00 (1)/ 2020-11-07 09:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ LOW GRADE FEVER (99-99.9)	2020-11-05 19:00 (1)/ 2020-11-07 09:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432597; Age (years): 72; Sex: F; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-05 19:00 (1)/ 2020-11-07 09:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432606; Age (years): 64; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-15 15:00 (1)/ 2020-10-17 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432632; Age (years): 50; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ INTERMITTENT MUSCLE SORENESS (LEFT ARM)	2020-11-01 (12)/ 2020-11-06 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442020; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-22 (8)/ 2020-09-22 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442021; Age (years): 30; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Vaccination site lymphadenopathy/ LEFT UNDERARM GLAND SWELLING/TENDERNESS (IPSILATERAL TO VACCINATION SITE)	2020-08-26 (9)/ 2020-08-28 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442023; Age (years): 25; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 (9)/ 2020-09-23 (9)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442031; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site warmth/ HEAT AT INJECTION SITE	2020-08-26 (9)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Vaccination site lymphadenopathy/ SWOLLEN LYMPH NODES RIGHT AXILLA-IPSILATERAL TO VACCINATION SITE	2020-08-26 (9)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-26 (9)/ 2020-08-27 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442031; Age (years): 55; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-08-26 (9)/ 2020-08-27 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3442055; Age (years): 31; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS NEAR INJECTION SITE- LEFT DELTOID NON URTICARIAL	2020-08-29 (9)/ 2020-08-31 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442097; Age (years): 63; Sex: F; Race: WHITE							
Vascular disorders/ Peripheral coldness/ COLD LEFT HAND	2020-09-23 20:00 (1)/ 2020-09-24 22:00 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442111; Age (years): 42; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 (9)/ 2020-09-10 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-09 (9)/ 2020-09-14 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-09 (9)/ 2020-09-15 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442122; Age (years): 56; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Chapped lips/ CHAPPED LIPS	2020-09-29 (2)/ 2020-10-03 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442122; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Facial discomfort/ FACIAL DISCOMFORT	2020-10-01 (4)/ 2020-10-03 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442128; Age (years): 41; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Axillary pain/ LEFT AXILLA DISCOMFORT	2020-09-30 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Axillary pain/ RIGHT AXILLA DISCOMFORT	2020-10-07 (9)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442139; Age (years): 37; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS: LEFT DELTOID, NON-URTICARIAL	2020-09-22 (9)/ 2020-09-23 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN: LEFT DELTOID	2020-09-22 (9)/ 2020-09-23 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE ITCHING: LEFT DELTOID	2020-09-22 (9)/ 2020-09-23 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442156; Age (years): 76; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-27 (8)/ 2020-10-27 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-27 (8)/ 2020-10-27 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHES	2020-10-27 (8)/ 2020-10-27 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3442164; Age (years): 60; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-10-14 14:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442164; Age (years): 60; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-19 (6)/ 2020-10-27 (14)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442178; Age (years): 39; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH UPPER BODY: NON-URTICARIAL	2020-09-18 (3)/ 2020-09-20 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ RASH UPPER EXTREMITIES: NON-URTICARIAL	2020-09-18 (3)/ 2020-09-20 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442178; Age (years): 39; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH UPPER BODY: NON-URTICARIAL	2020-10-16 (2)/ 2020-10-17 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3442220; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN: FINGERS, BILATERALLY IN KNEES AND ANKLES	2020-10-13 (7)/ 2020-10-28 (22)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3442227; Age (years): 56; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenitis/ UNDERARM GLAND SWELLING, IPSILATERAL TO INJECTION SITE	2020-10-21 (10)/ 2020-10-22 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452015; Age (years): 32; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-07-30 11:08 (1)/ 2020-08-07 23:59 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3452127; Age (years): 42; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-07 (5)/ 2020-08-15 (13)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3452162; Age (years): 54; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-07 (8)/ 2020-09-07 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452224; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Injection site cellulitis/ MILD CELLULITUS AT INJECTION SITE. LEFT ARM	2020-08-06 (2)/ 2020-08-20 (16)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452303; Age (years): 39; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-09 10:15 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 10:15 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-09 10:15 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 10:15 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452311; Age (years): 34; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-08 (1)/ 2020-09-15 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452368; Age (years): 44; Sex: M; Race: ASIAN							
Nervous system disorders/ Paraesthesia/ PARASTHESIA OF LEFT ARM	2020-09-17 (2)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3462058; Age (years): 39; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE PAST DAY 7	2020-09-03 17:00 (1)/ 2020-09-10 12:00 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462095; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-08 (1)/ 2020-09-22 (15)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462095; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-08 (1)/ 2020-09-25 (18)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-08 (1)/ 2020-10-03 (26)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-09 (2)/ 2020-09-30 (23)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462149; Age (years): 74; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-16 00:00 (7)/ 2020-09-18 00:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462158; Age (years): 22; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ POST-DOSE HEADACHE	2020-08-13 (1)/ 2020-08-22 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ POST-DOSE MUSCLE ACHES ALL OVER BODY	2020-08-13 (1)/ 2020-08-23 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462158; Age (years): 22; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ POST-DOSE CHILLS	2020-08-14 (2)/ 2020-08-20 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ POST-DOSE FATIGUE	2020-08-14 (2)/ 2020-08-22 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462178; Age (years): 29; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-14 20:00 (1)/ 2020-09-21 (8)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462178; Age (years): 29; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-14 20:00 (1)/ 2020-09-22 (9)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-14 20:00 (1)/ 2020-09-24 (11)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462193; Age (years): 29; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDER ARM GLAND SWELLING	2020-08-19 (6)/ 2020-08-22 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462217; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE POST-DOSE	2020-09-14 16:45 (1)/ 2020-09-14 20:30 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462274; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-19 10:00 (1)/ 2020-09-26 19:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ NAUSEA/VOMITING	2020-09-21 13:00 (4)/ 2020-09-26 18:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462277; Age (years): 54; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-09 17:00 (1)/ 2020-10-21 (13)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-10 (2)/ 2020-10-17 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462293; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ POST-DOSE CHILLS	2020-09-20 (6)/ 2020-10-05 (21)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462304; Age (years): 67; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-22 (2)/ 2020-09-28 16:00 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-22 (2)/ 2020-09-30 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 (2)/ 2020-09-30 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462314; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-21 18:00 (1)/ 2020-10-07 (17)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE	2020-09-21 18:00 (1)/ 2020-10-13 (23)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-09-21 18:00 (1)/ 2020-10-13 (23)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462320; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-02 (9)/ 2020-09-07 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462320; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITIS	2020-09-02 (9)/ 2020-09-07 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462392; Age (years): 52; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-31 18:00 (1)/ 2020-09-08 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462404; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-02 (2)/ 2020-09-09 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3472033; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-10 10:00 (1)/ 2020-10-10 23:59 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472035; Age (years): 55; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY (BILATERAL AXILLARY)	2020-10-04 (24)/ 2020-10-18 (38)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472036; Age (years): 56; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Axillary pain/ BILATERAL UNDERARM TENDERNESS	2020-09-14 (4)/ 2020-09-24 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3472048; Age (years): 42; Sex: F; Race: MULTIPLE: (b) (6)							
Skin and subcutaneous tissue disorders/ Rash/ NON URTICARIAL RASH - MIDDLE OF BACK	2020-09-22 (7)/ 2020-10-07 (22)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472048; Age (years): 42; Sex: F; Race: MULTIPLE: (b) (6)							
Skin and subcutaneous tissue disorders/ Rash/ NON URTICARIAL RASH - MIDDLE OF BACK	2020-10-16 (3)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3472062; Age (years): 61; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITIS	2020-10-22 (4)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3472094; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-11 (6)/ 2020-10-14 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482019; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-09 02:00 (1)/ 2020-09-09 15:00 (2)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482031; Age (years): 47; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Joint range of motion decreased/ LIMITED RANGE OF MOTION IN LEFT ARM	2020-08-12 22:00 (1)/ 2020-08-15 08:00 (3)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-09-29 (21)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3482032; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 08:00 (28)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482032; Age (years): 68; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ DIFFUSE MYALGIA	2020-09-10 08:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-10 08:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482064; Age (years): 71; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash macular/ NON-URTICARIAL MACULAR RASH WITH BLANCHING ERYTHEMA ON LEFT DELTOID	2020-08-25 (9)/ 2020-09-04 (19)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482069; Age (years): 31; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIC EPISODE	2020-09-15 17:22 (2)/ 2020-09-15 19:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482070; Age (years): 53; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES PAST DAY 7 OF REACTO PERIOD	2020-09-15 08:00 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3482078; Age (years): 72; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-29 16:00 (1)/ 2020-10-01 08:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482090; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ NON-URTICARIAL, MACULAR, REDNESS ON LEFT DELTOID AT THE INJECTION SITE	2020-09-16 15:51 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482090; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-17 12:05 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3482091; Age (years): 73; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIAS, GENERALIZED	2020-08-24 (6)/ 2020-08-28 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482103; Age (years): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-12 (23)/ 2020-09-25 (36)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482134; Age (years): 70; Sex: M; Race: WHITE							
Nervous system disorders/ Dysgeusia/ METALLIC TASTE	2020-09-29 (2)/ 2020-10-01 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482144; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 18:00 (1)/ 2020-10-07 12:00 (43)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES (ARTHRALGIAS)	2020-08-29 (4)/ 2020-10-07 (43)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482144; Age (years): 53; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES (MYALGIA)	2020-08-29 (4)/ 2020-10-07 (43)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING (AXILLARY LYMPHADENOPATHY IPSILATERAL TO INJECTION)	2020-08-30 (5)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482155; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-09-14 (19)/ 2020-09-25 (30)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482162; Age (years): 44; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY IPSILATERAL TO VACCINATION SITE	2020-09-25 17:00 (1)/ 2020-10-06 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482202; Age (years): 72; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-08 (7)/ 2020-09-20 (19)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482209; Age (years): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-01 (3)/ 2020-10-02 (4)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482209; Age (years): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ CONGESTION, NASAL	2020-10-01 (3)/ 2020-10-09 (11)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482234; Age (years): 81; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-04 (3)/ 2020-10-06 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-04 (3)/ 2020-10-06 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482279; Age (years): 74; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE, 6 CM X 1.5 CM	2020-09-21 (11)/ 2020-09-23 (13)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ DELAYED SWELLING AT SITE OF INJECTION	2020-09-21 (11)/ 2020-09-23 (13)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482309; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ LEFT DELTOID PAIN	2020-11-03 (15)/ 2020-11-14 (26)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482327; Age (years): 62; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-27 (5)/ 2020-11-02 (11)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-27 (5)/ 2020-11-02 (11)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-27 (5)/ 2020-11-02 (11)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492003; Age (years): 61; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ MUSCLE SORENESS AT INJECTION SITE	2020-08-25 (1)/ 2020-08-27 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492009; Age (years): 55; Sex: M; Race: WHITE							
Psychiatric disorders/ Insomnia/ INSOMNIA	2020-09-22 19:30 (1)/ 2020-09-26 07:00 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492010; Age (years): 73; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADED	2020-08-26 11:33 (1)/ 2020-08-26 13:05 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492010; Age (years): 73; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ CONTINUING LEFT ARM POST INJECTION DAY 1 SORENESS	2020-08-26 22:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-02 (8)/ 2020-09-03 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492024; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (21)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492056; Age (years): 63; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Malaise/ "FEELING OUT OF SORTS"	2020-09-03 15:45 (1)/ 2020-09-03 18:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492070; Age (years): 31; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-10 (7)/ 2020-09-15 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492173; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-15 13:30 (1)/ 2020-10-16 10:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492203; Age (years): 43; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-10-23 (8)/ 2020-10-30 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492214; Age (years): 28; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-25 (7)/ 2020-10-26 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492306; Age (years): 48; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Pyrexia/ FEVER - 100.3	2020-11-13 22:00 (1)/ 2020-11-13 23:59 (1)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492306; Age (years): 48; Sex: M; Race: ASIAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING OR TENDERNESS	2020-11-15 (3)/ 2020-11-15 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-11-15 (3)/ 2020-11-15 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-15 (3)/ 2020-11-15 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492306; Age (years): 48; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE - 7MM	2020-11-15 (3)/ 2020-11-15 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN TO INJECTION SITE	2020-11-15 (3)/ 2020-11-15 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE - 7MM	2020-11-15 (3)/ 2020-11-15 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492306; Age (years): 48; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-11-15 (3)/ 2020-11-15 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-11-15 (3)/ 2020-11-15 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-15 (3)/ 2020-11-15 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502058; Age (years): 44; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-26 06:00 (1)/ 2020-09-29 (5)	Yes/ Yes/ No	4	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502058; Age (years): 44; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY ADENOPATHY - IPSILATERAL	2020-09-28 (4)/ Ongoing	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3502148; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site discolouration/ INJECTION SITE DISCOLORATION	2020-10-14 (6)/ 2020-10-16 (8)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITUS	2020-10-14 (6)/ 2020-10-16 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502159; Age (years): 34; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT LYMPHADENOPATHY	2020-10-14 (3)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3502163; Age (years): 50; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE, LEFT DELTOID, NON-URTICARIAL	2020-09-24 (10)/ 2020-09-26 (12)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site macule/ ERYTHEMA AT INJECTION SITE, LEFT DELTOID, MACULAR	2020-09-24 (10)/ 2020-09-26 (12)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502187; Age (years): 42; Sex: M; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY	2020-10-26 (22)/ 2020-10-28 (24)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502209; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN	2020-11-14 01:00 (1)/ 2020-11-14 08:00 (1)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-14 01:00 (1)/ 2020-11-14 08:00 (1)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Hypoxia/ HYPOXIA	2020-11-14 01:00 (1)/ 2020-11-14 08:00 (1)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512002; Age (years): 53; Sex: F; Race: WHITE							
Nervous system disorders/ Hyperaesthesia/ GENERALIZED SKIN SENSITIVITY	2020-09-03 02:00 (1)/ 2020-09-03 14:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512008; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH LEFT DELTOID, NON-URTICARIAL; MACULOPAPULAR	2020-08-13 (9)/ 2020-08-18 (14)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE ITCHING LEFT DELTOID	2020-08-14 (10)/ 2020-08-15 (11)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512008; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INJECTION SITE INDURATION	2020-09-02 17:20 (1)/ 2020-09-13 13:01 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-02 17:20 (1)/ 2020-09-13 13:01 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-02 17:34 (1)/ 2020-09-13 12:01 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512025; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Malaise/ MALAISE	2020-09-03 18:30 (1)/ 2020-09-17 06:00 (14)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE JOINT ACHES	2020-09-05 (3)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512047; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ TENDERNESS AT INJECTION SITE	2020-08-21 (10)/ 2020-08-24 (13)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512047; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHINESS AT INJECTION SITE	2020-08-21 (10)/ 2020-08-27 (16)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-21 (10)/ 2020-08-27 (16)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE	2020-08-21 (10)/ 2020-08-28 (17)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512051; Age (years): 29; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-11 23:30 (2)/ 2020-09-12 07:30 (2)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512076; Age (years): 47; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENED BILATERAL LOW BACK PAIN	2020-09-21 (4)/ 2020-09-23 (6)	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ UPPER MIDDLE MUSCULOSKELETAL BACK PAIN	2020-09-24 (7)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512078; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 (7)/ 2020-09-19 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512107; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ IPSILATERAL INJECTION SITE LEFT SUPRATROCHLEAR LYMPHADENOPATHY	2020-09-18 19:00 (2)/ 2020-10-04 07:00 (17)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512120; Age (years): 55; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Swelling/ UNDERARM SWELLING IPSILATERAL	2020-08-22 02:00 (1)/ 2020-08-29 04:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512120; Age (years): 55; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES BILATERAL UPPER EXTREMITIES	2020-08-22 02:00 (1)/ 2020-08-30 04:00 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-22 02:00 (1)/ 2020-09-01 04:00 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-22 02:00 (1)/ 2020-09-01 04:00 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512171; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE ITCHINESS	2020-09-04 (9)/ 2020-09-07 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ RIGHT DELTOID INJECTION SITE ERYTHEMATOUS PATCH; NON-UTICARIAL	2020-09-04 (9)/ 2020-09-08 (13)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-04 (9)/ 2020-09-08 (13)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512174; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES GENERALIZED	2020-09-02 (7)/ 2020-09-04 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES GENERALIZED	2020-09-02 (7)/ 2020-09-04 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512177; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-29 20:02 (1)/ 2020-09-18 (21)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512177; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	2020-08-30 12:00 (2)/ 2020-08-31 07:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LEG MUSCLE ACHES	2020-09-25 22:00 (1)/ 2020-10-09 08:30 (14)	Yes/ No/ Yes	3	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-25 22:00 (1)/ 2020-10-15 08:30 (20)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512177; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP SORENESS	2020-09-27 (3)/ 2020-10-09 (15)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512200; Age (years): 77; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Tinnitus/ WORSENED BILATERAL TINNITUS	2020-09-03 05:30 (1)/ 2020-09-17 11:00 (15)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-03 06:00 (1)/ 2020-09-14 05:30 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512200; Age (years): 77; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-03 06:00 (1)/ 2020-09-14 05:30 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-03 06:00 (1)/ 2020-09-17 11:00 (15)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-03 06:00 (1)/ 2020-09-17 11:00 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-03 06:00 (1)/ 2020-09-17 11:00 (15)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512200; Age (years): 77; Sex: M; Race: WHITE							
Nervous system disorders/ Hypoaesthesia/ LEFT HAND 5TH FINGER NUMBNESS	2020-09-03 13:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Hypoaesthesia/ RIGHT HAND 4TH AND 5TH FINGER NUMBNESS	2020-09-03 13:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3512228; Age (years): 55; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-06 22:00 (2)/ 2020-09-07 10:00 (3)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512233; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE ITCHINESS RIGHT DELTOID	2020-09-12 (8)/ 2020-09-13 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512233; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ PAPULAR, URTICARIAL INJECTION SITE ERYTHEMA RIGHT DELTOID	2020-09-12 (8)/ 2020-09-13 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512239; Age (years): 37; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-08 07:00 (1)/ 2020-10-15 08:00 (8)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512240; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INJECTION SITE HARDNESS	2020-09-10 18:00 (2)/ 2020-09-17 20:00 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512246; Age (years): 37; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-10 08:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-11 (3)/ 2020-09-25 (17)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-09-14 (6)/ 2020-09-15 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512264; Age (years): 45; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-14 (3)/ 2020-09-20 (9)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512264; Age (years): 45; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (BILATERAL LEGS AND MID-BACK)	2020-09-14 (3)/ 2020-09-22 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL LOWER EXTREMITY JOINT ACHES	2020-09-18 (7)/ 2020-09-22 (11)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512274; Age (years): 75; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-26 (10)/ 2020-09-28 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512274; Age (years): 75; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site warmth/ INJECTION SITE WARMTH	2020-09-26 (10)/ 2020-09-28 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512287; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT ARM JOINT ACHES	2020-10-01 04:30 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Myalgia/ LEFT ARM MUSCLE ACHES	2020-10-01 04:30 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3512291; Age (years): 56; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-10-13 (6)/ 2020-10-13 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512291; Age (years): 56; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-13 (6)/ 2020-10-13 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522014; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-25 (21)/ 2020-08-26 (22)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522018; Age (years): 40; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ ARM PAIN	2020-08-13 (9)/ 2020-08-14 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522057; Age (years): 40; Sex: M; Race: WHITE							
Psychiatric disorders/ Insomnia/ DIFFICULTY SLEEPING	2020-09-09 (2)/ 2020-09-12 (5)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522063; Age (years): 58; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ TINGLING OF FACE (RIGHT SIDE)	2020-09-12 (5)/ 2020-09-12 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522103; Age (years): 44; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Joint range of motion decreased/ LIMITED RANGE OF MOTION OF LEFT ARM	2020-08-12 18:00 (1)/ 2020-08-12 23:00 (1)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ LEFT ARM RASH	2020-09-14 (4)/ 2020-09-15 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522107; Age (years): 63; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-03 (22)/ 2020-09-04 (23)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522108; Age (years): 68; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-15 (3)/ 2020-08-15 (3)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522109; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ PAIN IN UPPER RIGHT CHEST NOS	2020-09-14 (5)/ 2020-09-15 (6)	Yes/ Yes/ No	4	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522121; Age (years): 31; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ PAIN IN THE LOWER BACK	2020-09-17 07:00 (1)/ 2020-09-17 23:00 (2)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522122; Age (years): 27; Sex: F; Race: WHITE							
Psychiatric disorders/ Insomnia/ TROUBLE SLEEPING ON DAY 1 AND DAY 2	2020-09-18 20:00 (1)/ 2020-09-19 20:00 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522149; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 (11)/ 2020-09-08 (23)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522160; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER OF 101.5	2020-09-16 14:00 (2)/ 2020-09-17 12:00 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522161; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-18 09:00 (1)/ 2020-08-18 19:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522161; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE	2020-08-18 09:00 (1)/ 2020-08-19 12:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-18 09:00 (1)/ 2020-08-19 12:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522181; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pruritus/ ITCHYNESS AT INJECTION SITE	2020-09-16 17:00 (1)/ 2020-09-17 19:00 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522189; Age (years): 45; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-19 08:00 (1)/ 2020-09-20 08:00 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522191; Age (years): 34; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-22 (5)/ 2020-08-22 (5)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-18 (3)/ 2020-09-18 (3)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (3)/ 2020-09-18 (3)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522195; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-22 06:40 (1)/ 2020-09-25 11:59 (4)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-22 06:40 (1)/ 2020-09-25 11:59 (4)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522216; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-21 (6)/ 2020-09-21 (6)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522223; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-21 (1)/ 2020-09-21 12:52 (0)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522234; Age (years): 46; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-26 (3)/ 2020-09-27 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522237; Age (years): 34; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE IN FRONTAL AND TEMPORAL REGIONS (THROBBING AND TIGHTENING LASTING 5-10 SECONDS DAILY)	2020-08-21 (2)/ 2020-08-28 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522285; Age (years): 30; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATING	2020-09-18 20:00 (1)/ 2020-09-19 13:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522296; Age (years): 57; Sex: F; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-08-22 (2)/ 2020-08-24 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522302; Age (years): 33; Sex: F; Race: WHITE							
Investigations/ Body temperature increased/ TEMPERATURE INCREASED TO 100.8 WHICH WAS NOT RECORDED IN EDIARY	2020-09-22 21:00 (2)/ 2020-09-23 08:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522314; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER 100.3	2020-09-22 10:30 (1)/ 2020-09-22 12:00 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522373; Age (years): 71; Sex: M; Race: WHITE							
Investigations/ Prostatic specific antigen increased/ ELEVATED PSA	2020-10-30 (38)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3522396; Age (years): 30; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Hyperaesthesia/ SKIN SENSITIVITY	2020-09-26 09:00 (1)/ 2020-09-29 21:00 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522401; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ RIGHT THUMB ARTHRITIS	2020-09-11 (16)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522407; Age (years): 75; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ LEFT ARM PAIN AT INJECTION SITE AND CHILLS	2020-09-29 10:00 (1)/ 2020-09-30 06:00 (2)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522412; Age (years): 58; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SORE THROAT, SINUS CONGESTION	2020-10-04 10:00 (6)/ Ongoing	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3522418; Age (years): 75; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ SUBSTERNAL CHEST PAIN	2020-10-06 20:00 (2)/ 2020-10-07 05:31 (2)	Yes/ Yes/ No	4	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522435; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Hypoaesthesia/ FACIAL NUMBNESS, LEFT CHEEK, CHIN, AND FOREHEAD, UNKNOWN ETIOLOGY	2020-08-28 12:00 (1)/ 2020-08-28 12:01 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522437; Age (years): 75; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-08-29 (2)/ 2020-08-30 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522448; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ RECURRENT DIZZINESS	2020-09-30 (2)/ 2020-10-02 (4)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522457; Age (years): 63; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Tinnitus/ WORSENING OF TINNITUS	2020-09-01 09:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522457; Age (years): 63; Sex: M; Race: WHITE							
Investigations/ Heart rate increased/ ELEVATED HEART RATE FROM BASELINE	2020-09-01 09:00 (1)/ 2020-09-07 09:00 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Respiratory rate increased/ ELEVATED RR FROM BASELINE	2020-09-01 09:00 (1)/ 2020-09-07 09:00 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Psychiatric disorders/ Sleep disorder/ IRREGULAR SLEEP	2020-09-01 21:00 (2)/ 2020-09-07 09:00 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522463; Age (years): 81; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-07 (8)/ 2020-09-07 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522480; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-29 00:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3522510; Age (years): 66; Sex: F; Race: WHITE							
Nervous system disorders/ Essential tremor/ EXACERBATION OF EXISTING CONDITION-ESEENTIAL TREMORS	2020-10-06 09:00 (1)/ 2020-10-09 12:00 (5)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522518; Age (years): 69; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE DAY 8, DAY 9	2020-10-06 09:00 (1)/ 2020-10-13 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522521; Age (years): 27; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE DAY 8	2020-09-06 (5)/ 2020-10-06 (35)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522523; Age (years): 56; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Ear discomfort/ EAR PLUGGED	2020-10-03 09:30 (2)/ 2020-10-03 21:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-03 09:30 (2)/ 2020-10-03 21:30 (2)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522529; Age (years): 44; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE DAY 8 AND DAY 9	2020-09-10 (9)/ 2020-09-11 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY DAY 8	2020-10-14 (8)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522539; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE DAY 8, FATIGUE DAY 8	2020-09-12 (11)/ 2020-10-12 (41)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site joint pain/ JOINT ACHES DAY 8 AND DAY 9 AFTER 2ND INJECTION	2020-10-12 (8)/ 2020-10-13 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522562; Age (years): 57; Sex: M; Race: MULTIPLE: (b) (6)							
Skin and subcutaneous tissue disorders/ Psoriasis/ PSORIASIS EXACERBATION	2020-09-09 (7)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522565; Age (years): 58; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ GLANDS IN NECK SWOLLEN BILATERALLY	2020-09-05 (3)/ 2020-09-06 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522572; Age (years): 34; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Body temperature increased/ BODY TEMPERATURE OF 101.3 ON DAY TWO FOLLOWING SECOND INJECTION.	2020-10-09 12:00 (1)/ 2020-10-10 07:00 (2)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522573; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ LOW GRADE FEVER	2020-10-02 22:00 (1)/ 2020-10-04 08:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522581; Age (years): 28; Sex: M; Race: WHITE							
Psychiatric disorders/ Abnormal dreams/ "WEIRD" DREAMS	2020-09-30 22:00 (1)/ 2020-10-01 07:00 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ NOCTURNAL HYPERHIDROSIS	2020-09-30 23:00 (1)/ 2020-10-01 07:00 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522613; Age (years): 54; Sex: F; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-08 13:30 (1)/ 2020-09-21 14:00 (14)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-08 13:30 (1)/ 2020-10-19 21:00 (42)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522613; Age (years): 54; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ THROAT ITCHING	2020-09-09 (2)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3522615; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ CIRCULAR RASH AROUND INJECTION SITE WITH PRURITUS	2020-09-18 (11)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-07 08:00 (1)/ 2020-10-08 08:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522658; Age (years): 63; Sex: M; Race: WHITE							
Nervous system disorders/ Paraesthesia/ TINGLING DOWN ARM	2020-09-11 12:36 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522664; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RIGHT DELTOID MACULAR, NON-URTICARIAL REDNESS AT INJECTION SITE 120MM BY 86MM OBLONG	2020-09-23 (13)/ 2020-09-25 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522666; Age (years): 76; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA REMAINING AFTER 7 DAYS AFTER 2ND INJECTION	2020-10-12 17:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Hallucination/ HALLUCINATION	2020-10-13 03:00 (1)/ 2020-10-13 04:00 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522677; Age (years): 44; Sex: M; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-17 09:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Injection related reaction/ CHILLS DAY 8 POST 2ND INJECTION	2020-10-23 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE DAY 8 POST 2ND INJECTION	2020-10-23 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522684; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ MACULAR, NON-UTICARIAL REDNESS AT INJECTION SITE	2020-09-28 (14)/ 2020-10-01 (17)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532005; Age (years): 76; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 (11)/ 2020-09-28 (15)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532058; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA	2020-08-27 (10)/ 2020-09-03 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532058; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (1)/ 2020-09-25 (9)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532072; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT SHOULDER JOINT ACHES	2020-09-17 (2)/ 2020-09-25 (10)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ LEFT SHOULDER MUSCLE ACHES	2020-09-17 (2)/ 2020-09-25 (10)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532083; Age (years): 50; Sex: F; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE	2020-09-26 08:00 (1)/ 2020-09-26 11:00 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532086; Age (years): 69; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Joint stiffness/ LEFT ELBOW STIFFNESS	2020-09-18 00:00 (1)/ 2020-09-20 00:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532092; Age (years): 74; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ RASH ON LEFT ARM, MACULAR, URTICARIAL	2020-09-01 (13)/ 2020-09-06 (18)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532093; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA	2020-08-29 (10)/ 2020-09-15 (27)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532093; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA.	2020-09-22 (1)/ 2020-10-17 (26)	Yes/ No/ Yes	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532096; Age (years): 40; Sex: F; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Paraesthesia/ TINGLING SENSATION THROUGHOUT BODY.	2020-09-22 00:00 (1)/ 2020-09-23 00:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532108; Age (years): 66; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ OPTICAL HEADACHE	2020-09-24 (2)/ 2020-09-24 (2)	Yes/ Yes/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532113; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 (2)/ 2020-10-03 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532121; Age (years): 69; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE DAY 09	2020-09-29 (9)/ 2020-09-29 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532122; Age (years): 48; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH ON NECK AND ABDOMEN, NON-PAPULAR, NON- URTICARIAL	2020-08-26 (3)/ 2020-08-27 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ RASH ON NECK AND ABDOMEN, NON-PAPULAR, NON-URTICARIAL	2020-09-22 (2)/ 2020-09-23 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532145; Age (years): 82; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ NON-URTICARIAL PINKNESS AT INJECTION SITE	2020-09-06 (13)/ 2020-09-10 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532162; Age (years): 72; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL KNEE PAIN	2020-10-07 (16)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3532166; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 15:25 (1)/ 2020-10-05 12:42 (12)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532172; Age (years): 68; Sex: F; Race: WHITE							
Investigations/ Heart rate increased/ ELEVATED HEART RATE	2020-09-29 (2)/ 2020-09-30 (3)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532177; Age (years): 72; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ RED AREA ON BICEPT/TRICEPT AREA	2020-09-30 (3)/ 2020-10-14 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532233; Age (years): 67; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-05 (3)/ 2020-09-10 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532240; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 21:00 (1)/ 2020-10-08 (9)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532243; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 17:41 (2)/ 2020-10-15 00:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532259; Age (years): 32; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542014; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-09-15 (2)/ 2020-09-18 (5)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542033; Age (years): 44; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-17 (1)/ 2020-09-18 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542041; Age (years): 59; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-22 (2)/ 2020-08-23 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ PRURITIS AT INJECTION SITE	2020-09-07 (18)/ 2020-09-07 (18)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542050; Age (years): 42; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT AXILLARY LYMPHADENOPATHY (IPSILATERAL TO INJECTION SITE)	2020-10-06 (13)/ 2020-10-07 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542054; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-01 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPS	2020-09-24 (3)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542068; Age (years): 36; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-02 (8)/ 2020-09-23 (29)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542087; Age (years): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-08-29 (2)/ 2020-08-29 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542099; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITIS	2020-10-10 (11)/ 2020-10-12 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542108; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling face/ CHEEK SWELLING, BILATERAL	2020-09-30 10:00 (1)/ 2020-10-05 (7)	Yes/ Yes/ No	2	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542111; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-01 (3)/ 2020-10-01 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542139; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ LEFT ARM INJECTION SITE PAIN	2020-09-09 (7)/ 2020-09-09 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542146; Age (years): 36; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash papular/ PAPULAR RASH LEFT UPPER ARM NONURTICARIAL	2020-09-06 (4)/ 2020-11-02 (61)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILARY (IPSILATERAL TO INJECTION) LYMPHADENOPATHY	2020-09-30 (2)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3542206; Age (years): 71; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-10 17:02 (1)/ 2020-09-22 (13)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542219; Age (years): 38; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY (IPSILATERAL)	2020-09-29 (16)/ 2020-10-10 (27)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542223; Age (years): 58; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-19 (8)/ 2020-10-19 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-19 (8)/ 2020-10-20 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-19 (8)/ 2020-10-20 (9)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542227; Age (years): 55; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-10-12 (1)/ 2020-10-12 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542252; Age (years): 70; Sex: M; Race: WHITE							
Eye disorders/ Visual impairment/ VISUAL DISTURBANCE	2020-10-22 (1)/ 2020-10-22 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542258; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Peripheral swelling/ LEFT ARM SWELLING	2020-09-28 (12)/ 2020-10-01 (15)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Erythema/ LEFT ARM ERYTHEMA (NON-URTICARIAL/MACULAR)	2020-09-28 (12)/ 2020-10-01 (15)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542258; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Pruritus/ LEFT ARM PRURITUS	2020-09-28 (12)/ 2020-10-01 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542270; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ PRURITIS AT INJECTION SITE	2020-10-21 (3)/ 2020-10-22 (4)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542276; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-23 01:00 (1)/ 2020-09-30 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542276; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-23 01:00 (1)/ 2020-10-06 (15)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL ELBOWS AND RIGHT KNEE ARTHRALGIAS	2020-09-23 01:00 (1)/ 2020-10-06 (15)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIAS	2020-09-23 01:00 (1)/ 2020-10-06 (15)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542276; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (3)/ 2020-09-30 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-29 (8)/ 2020-09-29 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-03 (8)/ 2020-11-03 (8)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-11-03 (8)/ 2020-11-04 (9)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542276; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-03 (8)/ 2020-11-04 (9)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL ELBOWS AND RIGHT KNEE ARTHRLAGIAS	2020-11-03 (8)/ 2020-11-04 (9)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIAS	2020-11-03 (8)/ 2020-11-04 (9)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542285; Age (years): 74; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	2020-10-20 18:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3542293; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-20 (2)/ 2020-10-20 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542299; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-10-29 (2)/ 2020-10-30 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542304; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE PRURITIS	2020-10-06 (9)/ 2020-10-08 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542309; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-29 (2)/ 2020-10-29 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542312; Age (years): 46; Sex: M; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Hypoaesthesia/ LEFT ARM NUMBNESS	2020-10-12 (12)/ 2020-11-04 (35)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542317; Age (years): 36; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ INJECTION SITE ERYTHEMA - NON-URTICARIAL, MACULAR	2020-10-16 (12)/ 2020-10-20 (16)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-03 (2)/ 2020-11-04 (3)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542317; Age (years): 36; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Axillary pain/ LEFT AXILLA PAIN	2020-11-14 (13)/ 2020-11-14 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542318; Age (years): 69; Sex: F; Race: WHITE							
Vascular disorders/ Flushing/ FACIAL FLUSHING	2020-11-03 08:00 (1)/ 2020-11-03 14:00 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542326; Age (years): 71; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ BILATERAL CERVICAL LYMPHADENOPATHY	2020-10-13 (6)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542335; Age (years): 41; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-11-06 09:31 (1)/ 2020-11-06 10:15 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542354; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site erythema/ LEFT INJECTION SITE ERYTHEMA	2020-10-28 (8)/ 2020-10-31 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ LEFT INJECTION SITE PRURITUS	2020-10-28 (8)/ 2020-10-31 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542355; Age (years): 36; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymph node pain/ UNDERARM GLAND TENDERNESS	2020-10-29 (8)/ 2020-10-31 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552011; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-12 12:04 (1)/ 2020-08-20 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552044; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	2020-08-21 (7)/ 2020-08-23 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552050; Age (years): 55; Sex: F; Race: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-17 16:56 (1)/ 2020-08-25 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-08-18 16:44 (2)/ 2020-08-25 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552050; Age (years): 55; Sex: F; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-08-18 16:44 (2)/ 2020-08-25 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552052; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Eye disorders/ Blepharospasm/ RIGHT EYE TWITCHING	2020-08-19 (3)/ 2020-09-22 (37)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552053; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-15 12:00 (1)/ 2020-09-21 (8)	Yes/ Yes/ Yes	4	Yes/3 (2020-09-17/ 2020-09-18)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ INTRACTABLE VOMITING	2020-09-15 12:00 (1)/ 2020-09-21 (8)	Yes/ Yes/ Yes	4	Yes/3 (2020-09-17/ 2020-09-18)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552053; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-19 (6)/ 2020-09-19 (6)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552063; Age (years): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Alopecia/ HAIR LOSS	2020-09-24 (10)/ 2020-10-23 (39)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552100; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ INTERMITTENT DIZZINESS	2020-10-09 (22)/ 2020-11-06 (50)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552116; Age (years): 53; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-16 (3)/ 2020-09-16 (3)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552131; Age (years): 65; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ RASH ON NECK AND SHOULDERS- MACULAR AND URTICARIAL	2020-09-30 (13)/ 2020-10-06 (19)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552145; Age (years): 46; Sex: M; Race: ASIAN							
Psychiatric disorders/ Abnormal dreams/ VIVID DREAMS	2020-08-24 22:00 (1)/ 2020-08-31 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Psychiatric disorders/ Insomnia/ INSOMNIA	2020-08-24 22:00 (1)/ 2020-08-31 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Psychiatric disorders/ Insomnia/ INSOMNIA	2020-09-26 (6)/ 2020-10-03 (13)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552155; Age (years): 46; Sex: M; Race: MULTIPLE:						(b) (6)	
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-25 19:21 (1)/ 2020-09-06 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-25 19:21 (1)/ 2020-09-06 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552161; Age (years): 30; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ GENERALIZED BODY ACHES	2020-09-03 (10)/ 2020-09-05 (12)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552181; Age (years): 66; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-31 (6)/ 2020-09-02 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552189; Age (years): 21; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 15:04 (1)/ 2020-09-15 (21)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-08-27 15:04 (1)/ 2020-09-15 (21)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 15:04 (1)/ 2020-09-17 (23)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL AXILLARY LYMPHADENOPATHY	2020-08-28 (3)/ 2020-09-05 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552189; Age (years): 21; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-01 (7)/ 2020-09-06 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552191; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 18:42 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH ON EXERTION	2020-09-30 (8)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-09/ 2020-10-10)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552191; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Oedema peripheral/ BILATERAL ANKLE EDEMA	2020-10-06 (14)/ 2020-10-31 (39)	Yes/ No/ No	4	Yes/3 (2020-10-09/ 2020-10-10)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-08 (16)/ 2020-10-08 (16)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-08 (16)/ 2020-10-08 (16)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-08 (16)/ 2020-10-08 (16)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552191; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS	2020-10-09 (17)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA	2020-10-09 (17)/ 2020-11-09 (48)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552259; Age (years): 60; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-01 (4)/ 2020-10-08 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-07 (10)/ 2020-10-07 (10)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552262; Age (years): 33; Sex: M; Race: UNKNOWN							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-07 08:00 (1)/ 2020-10-07 20:00 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552302; Age (years): 34; Sex: M; Race: WHITE							
Nervous system disorders/ Somnolence/ GROGGINESS	2020-09-04 (3)/ 2020-09-16 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552355; Age (years): 53; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-10 (3)/ 2020-09-16 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552385; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Axillary pain/ INTERMITTENT LEFT AXILLA PAIN	2020-10-07 08:00 (1)/ 2020-10-22 (17)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552389; Age (years): 28; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Paraesthesia/ TINGLING IN LEFT ARM AFTER VACCINATION WITH MOVEMENT	2020-09-10 (1)/ 2020-09-12 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552434; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-21 (7)/ 2020-09-23 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-21 (7)/ 2020-09-23 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552497; Age (years): 22; Sex: F; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash/ RASH TO LEFT ARM	2020-10-03 (8)/ 2020-10-06 (11)	Yes/ No/ No	1	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552499; Age (years): 73; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-27 22:41 (2)/ 2020-10-06 17:55 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-27 22:41 (2)/ 2020-10-07 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-27 22:41 (2)/ 2020-10-10 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552524; Age (years): 45; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-19 (11)/ 2020-10-20 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3562088; Age (years): 41; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ GENERAL CHEST WALL PAIN	2020-08-27 17:15 (1)/ 2020-08-27 17:20 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3562133; Age (years): 33; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING OR TENDERNESS	2020-09-16 (8)/ 2020-09-20 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562184; Age (years): 22; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ BRUISE LEFT AXILLARY	2020-10-19 (5)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3562190; Age (years): 63; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ PARESTHESIA LEFT HAND	2020-10-22 12:53 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3562223; Age (years): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-13 (8)/ 2020-11-13 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572003; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-17 (4)/ 2020-09-18 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572013; Age (years): 33; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING ON ARMS AND LEGS	2020-08-20 (3)/ 2020-08-22 (5)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA @ INJECTION SITE (ONE RAISED, RED AREA- MACULAR NON-URTICARIAL)	2020-08-26 (9)/ 2020-08-26 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572071; Age (years): 22; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-24 17:00 (1)/ 2020-09-09 09:00 (16)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572096; Age (years): 42; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJ SITE	2020-09-02 (8)/ 2020-09-03 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Migraine/ MIGRAINE	2020-09-25 08:00 (1)/ 2020-09-26 20:00 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572097; Age (years): 38; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING	2020-08-28 00:00 (2)/ 2020-08-28 00:01 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572129; Age (years): 33; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-29 02:00 (1)/ 2020-08-30 08:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572129; Age (years): 33; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-03 (7)/ 2020-09-05 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572142; Age (years): 57; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES- LEFT SHOULDER	2020-09-30 (7)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3572166; Age (years): 72; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOLS	2020-09-02 17:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572166; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT THE INJECTION SITE	2020-10-05 (5)/ 2020-10-07 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572189; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE (RIGHT SIDE SCALP TENDERNESS)	2020-09-10 (7)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3572287; Age (years): 39; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Paranasal sinus discomfort/ SINUS PRESSURE	2020-09-17 (4)/ 2020-09-20 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572291; Age (years): 55; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-10 (2)/ 2020-10-11 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572350; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS ON INJECTION SITE LEFT DELTOID, NON URTICARIAL	2020-10-02 (8)/ 2020-10-04 (10)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582022; Age (years): 33; Sex: F; Race: UNKNOWN							
Nervous system disorders/ Hypoaesthesia/ INTERMITTENT NUMBNESS/TINGLING IN LEFT ARM	2020-08-22 00:00 (1)/ 2020-08-31 00:00 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582049; Age (years): 48; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-21 22:00 (1)/ 2020-09-22 07:00 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582050; Age (years): 26; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-28 19:30 (1)/ 2020-09-29 08:00 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-28 19:30 (1)/ 2020-09-29 08:00 (1)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582060; Age (years): 73; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ REDNESS AT INJECTION SITE - MACULOPAPULAR RASH, NON-URTICARIAL	2020-09-05 (10)/ 2020-09-12 (17)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582070; Age (years): 68; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ CERVICAL LYMPHADENOPATHY, RIGHT	2020-09-11 (15)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Flank pain/ FLANK PAIN, LEFT SIDED	2020-09-25 (2)/ 2020-09-28 (5)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582070; Age (years): 68; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ BACK SPASMS	2020-09-25 (2)/ 2020-09-28 (5)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3582072; Age (years): 42; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN, BILATERAL HIPS	2020-08-28 18:59 (1)/ 2020-09-05 12:00 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN, RIGHT SHOULDER	2020-08-28 18:59 (1)/ 2020-09-05 12:00 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582072; Age (years): 42; Sex: F; Race: WHITE							
Psychiatric disorders/ Abnormal dreams/ VIVID DREAMS	2020-08-29 00:00 (1)/ 2020-09-09 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582090; Age (years): 41; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	2020-09-30 03:30 (1)/ 2020-09-30 03:35 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582105; Age (years): 33; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 19:00 (1)/ 2020-10-03 12:00 (2)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582114; Age (years): 40; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT (INJECTION SIDE) AXILLARY LYMPHADENOPATHY	2020-09-08 18:00 (1)/ 2020-10-06 23:59 (29)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT PAIN ONGOING AFTER DAY 7	2020-09-09 (2)/ 2020-10-06 (29)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA ONGOING AFTER DAY 7	2020-09-13 (6)/ 2020-10-06 (29)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582114; Age (years): 40; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (LEFT DELTOID), ERYTHEMA ONLY WITHOUT URTICARIA OR RASH.	2020-09-15 (8)/ 2020-09-20 (13)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-15 (8)/ 2020-09-20 (13)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582126; Age (years): 34; Sex: M; Race: MULTIPLE: (b) (6)							
Skin and subcutaneous tissue disorders/ Rash maculo-papular/ MACULOPAPULAR LEFT SHOULDER (DELTOID) RASH, NON-URTICARIAE	2020-09-18 (10)/ 2020-09-20 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582127; Age (years): 30; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY AXILLARY (LEFT SIDE) INJECTION SIDE	2020-09-16 (8)/ 2020-09-21 (13)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-17 (9)/ 2020-09-20 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash maculo-papular/ LEFT UPPER ARM RASH, MACULOPAPULAR, NON-URTICARIAL	2020-09-17 (9)/ 2020-09-25 (17)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582127; Age (years): 30; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (RIGHT DELTOID)	2020-10-08 (3)/ 2020-10-15 (10)	Yes/ No/ Yes	1	No	R/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582134; Age (years): 36; Sex: M; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY, LEFT LEG	2020-09-14 (5)/ 2020-09-17 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-09-15 (6)/ 2020-09-17 (8)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582137; Age (years): 36; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-11 10:00 (1)/ 2020-09-20 08:00 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-11 16:00 (1)/ 2020-09-19 12:00 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582167; Age (years): 29; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOLS	2020-10-08 (9)/ 2020-10-08 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3592137; Age (years): 37; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-11 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592137; Age (years): 37; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-11 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592216; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-08-24 (8)/ 2020-08-25 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602003; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAINFUL LEFT DELTOID AREA X 4 DAYS AFTER RECEIVING INVESTIGATIONAL PRODUCT	2020-09-01 21:00 (1)/ 2020-09-05 07:00 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: REMAINING EFFECT PER EMR IS : "DENIES SWELLING AT INJECTION SITE"

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602003; Age (years): 46; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Joint range of motion decreased/ LIMITED ROM AND ELEVATION OF LEFT ARM	2020-10-02 09:00 (2)/ 2020-10-04 09:00 (4)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602007; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-10-06 08:00 (1)/ 2020-10-06 19:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-06 08:00 (1)/ 2020-10-06 19:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602007; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ LOW GRADE TEMP	2020-10-06 08:00 (1)/ 2020-10-06 19:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602013; Age (years): 57; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Alopecia/ HAIR LOSS	2020-09-06 (4)/ 2020-09-06 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	
General disorders and administration site conditions/ Pyrexia/ FEVER (TEMPERATURE > OR = 100.4 DEGREES FAHRENHEIT)	2020-09-30 08:00 (1)/ 2020-10-02 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602013; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ RECURRENT SINUSITIS (SINUS INFECTION)	2020-10-20 (22)/ 2020-10-24 (26)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602017; Age (years): 45; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Injection site pain/ MUSCLE PAIN AT INJECTION SITE	2020-09-30 17:00 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-06 (7)/ 2020-10-07 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602017; Age (years): 45; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA (RUNNY NOSE)	2020-10-06 (7)/ 2020-10-07 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602023; Age (years): 60; Sex: M; Race: UNKNOWN							
Infections and infestations/ Oral herpes/ COLD SORE	2020-10-13 (5)/ 2020-10-15 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602035; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-13 06:00 (1)/ 2020-10-14 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602043; Age (years): 22; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling/ UNDERARM SWELLING (TO THE LEFT ARM)	2020-09-19 (5)/ 2020-09-24 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602045; Age (years): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Axillary pain/ UNDERARM PAIN	2020-09-16 18:00 (1)/ 2020-09-20 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE SORENESS IN THE HAND	2020-09-16 18:00 (1)/ 2020-09-20 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602045; Age (years): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Reproductive system and breast disorders/ Menstrual disorder/ ABNORMAL MENSTRUATION (LASTING >7 DAYS AND HEAVY VS NORMALLY 5 DAYS)	2020-10-01 (16)/ 2020-10-12 (27)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602050; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pruritus/ PRURITIS (ITCHING) AT THE INJECTION SITE	2020-09-25 (9)/ 2020-09-26 (10)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602056; Age (years): 50; Sex: M; Race: UNKNOWN							
General disorders and administration site conditions/ Pyrexia/ FEVER (101.2 F)	2020-10-17 06:00 (1)/ 2020-10-17 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602061; Age (years): 47; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site erythema/ REDNESS TO THE INJECTION SITE (LEFT DELTOID)	2020-09-18 18:00 (1)/ 2020-09-19 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ SORE ARM	2020-10-17 07:00 (1)/ 2020-10-20 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602062; Age (years): 35; Sex: M; Race: UNKNOWN							
Musculoskeletal and connective tissue disorders/ Axillary mass/ UNDERARM LUMP - REPORTED ON SAFETY CALL #8	2020-09-19 07:00 (1)/ 2020-09-20 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602062; Age (years): 35; Sex: M; Race: UNKNOWN							
Musculoskeletal and connective tissue disorders/ Axillary mass/ PAINFUL R UNDERARM LUMP REPORTED ON DAY 11	2020-09-19 07:00 (1)/ 2020-09-21 07:00 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Eye disorders/ Vision blurred/ BLURRY VISION BILATERAL X 1.5 HR - SELF RESOLVED . LAST OPTHALM CHECK UP 3 MONTHS AGO AND WAS NORMAL	2020-10-01 19:00 (14)/ 2020-10-01 20:30 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT AXILLARY-CONTRALATERAL (OPPOSITE INJECTION SITE) LYMPHADENOPATHY	2020-11-19 13:15 (34)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602064; Age (years): 51; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE LYMPHADENOPATHY	2020-10-17 (2)/ 2020-10-24 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602098; Age (years): 33; Sex: M; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ "SCRATCHY-ITCHY" THROAT	2020-10-15 (8)/ 2020-10-17 (10)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602104; Age (years): 52; Sex: F; Race: OTHER: UNKNOWN							
Musculoskeletal and connective tissue disorders/ Myalgia/ LEFT DELTOID PAIN WITHOUT REDNESS OR SWELLING	2020-10-23 (1)/ 2020-10-25 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602106; Age (years): 59; Sex: F; Race: OTHER: UNKNOWN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-25 20:00 (1)/ 2020-09-26 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Malaise/ MALAISE	2020-09-25 20:00 (1)/ 2020-09-26 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602122; Age (years): 56; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site pruritus/ 2 X 3 CM ITCHING AT THE INJECTION SITE	2020-10-10 06:00 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602122; Age (years): 56; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site rash/ 2 X 3 CM RASH AT THE INJECTION SITE	2020-10-10 06:00 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Chills/ CHILLS - REPORTED IN SAFETY CALL DAY #36	2020-10-29 14:00 (1)/ 2020-11-01 06:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS TO THE INJECTION SITE - REPORTED IN SAFETY CALL DAY #36	2020-10-29 14:00 (1)/ 2020-11-01 06:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602134; Age (years): 36; Sex: F; Race: UNKNOWN							
General disorders and administration site conditions/ Vaccination site lymphadenopathy/ AXILLARY LYMPHADENOPATHY (LEFT ARM, IPSILATERAL TO VACCINATION SITE)	2020-10-14 (8)/ 2020-10-21 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA (REDNESS) AT INJECTION SITE (NON URTICARIAL)	2020-11-04 18:00 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602134; Age (years): 36; Sex: F; Race: UNKNOWN							
General disorders and administration site conditions/ Injection site induration/ INDURATION (HARDNESS) AT INJECTION SITE	2020-11-04 18:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE (LEFT DELTOID)	2020-11-04 18:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3602144; Age (years): 50; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Musculoskeletal stiffness/ HARDNESS TO LEFT DELTOID	2020-10-13 15:00 (1)/ 2020-10-16 (4)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602147; Age (years): 53; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Musculoskeletal stiffness/ L SHOULDER STIFFNESS	2020-10-14 18:00 (1)/ 2020-10-17 07:00 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3612004; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RETICULATE MACULAR ERYTHEMA AT INJECTION SITE, RIGHT ARM	2020-09-07 (8)/ 2020-09-11 (12)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3612021; Age (years): 72; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 06:00 (1)/ 2020-09-09 12:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622010; Age (years): 54; Sex: F; Race: WHITE							
Nervous system disorders/ Dysgeusia/ BITTER TASTE	2020-09-08 15:00 (1)/ 2020-09-15 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622016; Age (years): 50; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-18 (10)/ 2020-09-18 (10)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (10)/ 2020-09-18 (10)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622028; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-14 20:00 (1)/ 2020-08-21 (8)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622041; Age (years): 67; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC PATCH/RASH	2020-09-17 (3)/ 2020-09-24 (10)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622050; Age (years): 48; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA (FULL BODY)	2020-08-28 (9)/ 2020-08-28 (9)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-28 (9)/ 2020-08-30 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622050; Age (years): 48; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES MYALGIA (FULL BODY)	2020-08-28 (9)/ 2020-08-30 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHES	2020-08-28 (9)/ 2020-08-30 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site bruising/ BRUISING AT INJECTION SITE	2020-09-17 08:57 (1)/ 2020-10-01 (15)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622051; Age (years): 57; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATS	2020-09-16 08:00 (1)/ 2020-09-18 (4)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622057; Age (years): 38; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-01 (9)/ 2020-09-03 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622074; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INDURATION AT INJECTION SITE	2020-09-22 12:05 (1)/ 2020-09-25 (4)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622080; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INDURATION AT INJECTION SITE	2020-09-23 08:10 (1)/ 2020-09-24 (2)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622082; Age (years): 48; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ HIVE	2020-09-02 (8)/ 2020-09-02 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622088; Age (years): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-29 (3)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622088; Age (years): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-24 (1)/ 2020-09-27 (4)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622117; Age (years): 56; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (5)/ 2020-10-06 (9)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622131; Age (years): 47; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ R. SHOULDER PAIN	2020-09-02 20:00 (1)/ 2020-09-04 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622171; Age (years): 41; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-18 (10)/ 2020-09-18 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622223; Age (years): 48; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-22 02:00 (1)/ 2020-10-22 08:00 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622224; Age (years): 54; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-24 (3)/ 2020-10-24 (3)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622229; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site mass/ RED LUMP AT INJECTION SITE	2020-10-08 (14)/ 2020-10-09 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-10-08 (14)/ 2020-10-09 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622230; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ RED BUMP AT INJECTION SITE	2020-10-08 (14)/ 2020-10-10 (16)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622270; Age (years): 62; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ RIGHT LEG MUSCLE ACHE	2020-10-14 08:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632009; Age (years): 64; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-26 (4)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3632027; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ LEFT ARM (NON-URTICARIAL) INJECTION SITE RED PATCH	2020-09-09 (10)/ 2020-09-11 (12)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632038; Age (years): 74; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-05 11:00 (1)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632052; Age (years): 61; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-08 11:38 (1)/ 2020-10-06 (29)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632053; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-08 11:55 (1)/ 2020-10-06 (29)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632058; Age (years): 37; Sex: F; Race: NOT REPORTED							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ HAND AND FEET CRAMPING	2020-10-07 01:01 (1)/ 2020-10-07 22:02 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632058; Age (years): 37; Sex: F; Race: NOT REPORTED							
Cardiac disorders/ Sinus tachycardia/ INAPPROPRIATE SINUS TACHYCARDIA	2020-10-23 (18)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3632066; Age (years): 66; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Hyperaesthesia/ SKIN SENSITIVITY	2020-10-07 (3)/ 2020-10-08 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632083; Age (years): 61; Sex: F; Race: MULTIPLE: (b) (6)							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-10-10 00:00 (1)/ 2020-10-10 23:50 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Syncope/ SYNCOPE	2020-10-10 08:00 (1)/ 2020-10-10 23:50 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632101; Age (years): 24; Sex: M; Race: OTHER: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ SUPRACLAVICULAR LYMPHADENOPATHY	2020-09-28 (7)/ 2020-10-10 (19)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	2020-10-22 (3)/ 2020-10-23 (4)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632106; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 (3)/ 2020-10-02 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632113; Age (years): 62; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Aphthous ulcer/ CANKER SORE FLARE UP	2020-10-16 (5)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632147; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-10-21 11:27 (1)/ 2020-11-11 00:00 (21)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-10-21 11:27 (1)/ 2020-11-11 00:00 (21)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3642055; Age (years): 66; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-31 (3)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642123; Age (years): 72; Sex: F; Race: WHITE							
Psychiatric disorders/ Suicidal ideation/ SUICIDAL IDEATION	2020-10-04 (2)/ 2020-10-04 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3642250; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH FROM VACCINE #1	2020-09-26 (8)/ 2020-09-29 (11)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3642268; Age (years): 38; Sex: M; Race: WHITE							
Nervous system disorders/ Neuropathy peripheral/ NEUROPATHY	2020-09-21 (1)/ 2020-11-04 (45)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3642295; Age (years): 23; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-03 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642312; Age (years): 46; Sex: F; Race: MULTIPLE:					(b) (6)		
Nervous system disorders/ Headache/ HEADACHE	2020-10-14 (2)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ ACID REFLUX	2020-11-01 (20)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3652001; Age (years): 70; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-08-26 (1)/ 2020-08-27 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652005; Age (years): 68; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-01 14:13 (1)/ 2020-09-08 23:59 (8)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652005; Age (years): 68; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-29 13:15 (1)/ 2020-09-29 13:40 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
			1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652007; Age (years): 71; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Feeling hot/ GENERALIZED SENSATION OF WARMTH	2020-09-08 12:25 (1)/ 2020-09-08 12:50 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652010; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT UNDERARM LYMPHADENOPATHY (EDIARY, IPSILATERAL)	2020-09-15 (6)/ 2020-09-20 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652013; Age (years): 75; Sex: F; Race: UNKNOWN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-10-12 (6)/ 2020-10-12 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3652023; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-10-13 (2)/ 2020-10-17 (6)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
			1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-10-13 (2)/ 2020-10-17 (6)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652024; Age (years): 26; Sex: M; Race: MULTIPLE:					(b) (6)		
Musculoskeletal and connective tissue disorders/ Limb discomfort/ ARM HEAVINESS	2020-10-13 14:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ ARM PAIN	2020-10-13 14:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3652030; Age (years): 31; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Limb discomfort/ ARM "HEAVINESS"	2020-09-29 15:00 (1)/ 2020-10-02 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652030; Age (years): 31; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER 100.9F	2020-10-07 (9)/ 2020-10-08 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652037; Age (years): 56; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ RIGORS	2020-09-26 (2)/ 2020-09-26 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3652047; Age (years): 24; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE (EDIARY)	2020-10-08 (7)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652047; Age (years): 24; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING OR TENDERNESS (EDIARY)	2020-10-09 (8)/ 2020-10-10 (9)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652050; Age (years): 36; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE (EDIARY)	2020-10-07 11:07 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3652052; Age (years): 22; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Fatigue/ FATIGUE (EDIARY)	2020-10-22 (7)/ 2020-10-23 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662002; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ SLIGHT ITCHY FEELING AROUND INJECTION SITE	2020-10-08 (4)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662024; Age (years): 41; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Taste disorder/ ALTERED TASTE	2020-09-14 12:15 (1)/ 2020-09-14 19:00 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Taste disorder/ ALTERED TASTE	2020-10-12 15:30 (1)/ 2020-10-12 18:30 (1)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662042; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ BRUISING AT INJECTION SITE	2020-09-13 (4)/ 2020-10-01 (22)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662050; Age (years): 54; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-09-29 (26)/ 2020-10-02 (29)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-02 21:30 (1)/ 2020-10-03 14:50 (2)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662050; Age (years): 54; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-03 12:00 (2)/ 2020-10-03 14:50 (2)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662052; Age (years): 72; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ PAIN, BACK OF NECK	2020-10-05 18:00 (1)/ 2020-10-06 08:00 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Poor quality sleep/ NOT SLEEPING WELL	2020-10-05 18:00 (1)/ 2020-10-06 08:00 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662055; Age (years): 39; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER, TMAX 100.8	2020-10-07 (2)/ 2020-10-07 (2)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662058; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-13 (6)/ 2020-09-20 (13)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662100; Age (years): 50; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Non-cardiac chest pain/ SHOOTING PAIN THROUGH BACK TO CHEST, NON CARDIAC	2020-09-16 08:47 (1)/ 2020-09-16 08:57 (1)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Flushing/ FLUSHING, FACE/NECK	2020-09-16 08:47 (1)/ 2020-09-16 08:57 (1)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662102; Age (years): 64; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-17 (2)/ 2020-09-17 (2)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662107; Age (years): 42; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 12:00 (1)/ 2020-09-17 23:00 (2)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-21 (6)/ 2020-09-23 (8)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-10-15 20:00 (1)/ 2020-10-16 21:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662115; Age (years): 40; Sex: M; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SLIGHT DIFFUCLTY BREATHING	2020-10-20 08:00 (1)/ 2020-10-20 17:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662115; Age (years): 40; Sex: M; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SLIGHT SHORTNESS OF BREATH	2020-10-20 08:00 (1)/ 2020-10-20 17:00 (2)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY AND ITCHY NOSE	2020-10-20 10:00 (1)/ 2020-10-23 10:00 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-10-20 10:00 (1)/ 2020-10-23 10:00 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662126; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Eye disorders/ Vitreous floaters/ SEEING BLACK FLOATER SPOTS IN VISION	2020-10-23 (3)/ 2020-11-10 (21)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662134; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN, DISSEMINATED	2020-09-30 (7)/ 2020-10-02 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES, DISSEMINATED	2020-09-30 (7)/ 2020-10-02 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662138; Age (years): 32; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ TENDERNESS ON INJECTION ARM	2020-09-26 17:00 (2)/ 2020-10-01 08:00 (6)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Hyperaesthesia/ EXTRA SKIN SENSITIVITY ON LEFT LOWER RIB CAGE	2020-09-27 (3)/ 2020-10-03 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Skin burning sensation/ SLIGHT BURNING SENSATION ON SKIN, LEFT LOWER RIB CAGE	2020-09-27 (3)/ 2020-10-03 (9)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662138; Age (years): 32; Sex: M; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHES	2020-10-24 18:00 (2)/ Ongoing	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662149; Age (years): 57; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Hyperaesthesia teeth/ TOOTH SENSITIVITY TO HOT/COLD	2020-10-03 (3)/ 2020-10-14 (14)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Toothache/ TOOTH ACHE, MOVES AROUND IN MOUTH, NOT ONE SPECIFIC AREA	2020-10-03 (3)/ 2020-10-14 (14)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662177; Age (years): 41; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ SORENESS AT STUDY MED INJECTION SITE, LEFT ARM	2020-10-26 (7)/ 2020-10-30 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ TENDERNESS AT STUDY MED INJECTION SITE, LEFT ARM	2020-10-26 (7)/ 2020-10-30 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672003; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT SITE OF INJECTION (LEFT ARM)	2020-08-14 (9)/ 2020-08-16 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672003; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site urticaria/ (PAPULAR URTICARIA) REDNESS @ SITE OF INJECTION (LEFT ARM)	2020-08-14 (9)/ 2020-08-17 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672082; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-11 16:44 (1)/ 2020-09-19 17:34 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672092; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (L)	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672092; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE (L)	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672093; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT SITE OF INJECTION (LEFT ARM)	2020-08-23 (11)/ 2020-08-25 (13)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site induration/ INDURATION AT SITE OF INJECTION (LEFT ARM)	2020-08-23 (11)/ 2020-08-25 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672100; Age (years): 52; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-13 16:59 (1)/ 2020-08-22 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-08-13 20:50 (1)/ 2020-08-21 00:09 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-13 20:51 (1)/ 2020-08-22 12:30 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-18 (6)/ 2020-08-22 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672100; Age (years): 52; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-10 21:09 (1)/ 2020-09-21 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (8)/ 2020-09-23 (14)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672163; Age (years): 56; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ RIGHT ARM ERYTHEMA (URTICARIAL)	2020-08-26 (9)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672163; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Induration/ RIGHT ARM INDURATION	2020-08-26 (9)/ 2020-09-02 (16)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672168; Age (years): 76; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-08-19 14:22 (1)/ 2020-08-26 20:22 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672178; Age (years): 22; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Axillary pain/ LEFT UNDERARM PAIN	2020-09-21 22:07 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672205; Age (years): 24; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUIE	2020-09-16 (2)/ 2020-09-24 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672209; Age (years): 40; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ SHOULDER PAIN	2020-09-17 00:00 (29)/ 2020-09-20 (33)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672249; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 (7)/ 2020-08-29 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672249; Age (years): 74; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-23 17:25 (1)/ 2020-09-30 16:01 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-23 17:25 (1)/ 2020-10-02 08:33 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-01 (9)/ 2020-10-03 (11)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672251; Age (years): 42; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-08-28 (8)/ 2020-08-30 (10)	Yes/ No/ Yes	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672255; Age (years): 32; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-08-22 13:18 (1)/ 2020-09-15 22:22 (26)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 (7)/ 2020-09-21 (32)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672255; Age (years): 32; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-22 16:40 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 16:40 (1)/ 2020-10-01 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-22 16:40 (1)/ 2020-10-09 00:03 (17)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672314; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT SIGHT OF INJECTION (LEFT ARM)	2020-09-03 (9)/ 2020-09-04 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672316; Age (years): 60; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-24 00:00 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3672325; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-29 (2)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672325; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-29 (2)/ 2020-10-06 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-29 (2)/ 2020-10-08 (11)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672351; Age (years): 77; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-02 (7)/ 2020-09-07 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672351; Age (years): 77; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-09-02 (7)/ 2020-09-07 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-09-02 (7)/ 2020-09-07 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672363; Age (years): 42; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-02 (7)/ 2020-09-05 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672377; Age (years): 31; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-28 20:48 (1)/ 2020-09-06 00:00 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672377; Age (years): 31; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ GENERALIZED PRURITIS	2020-09-11 (15)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Angioedema/ ANGIOEDEMA	2020-09-18 (22)/ 2020-09-19 (23)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ WORSENING OF URITICARIA	2020-09-21 (25)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Mechanical urticaria/ WORSENING OF DERMATOGRAPHIA	2020-09-21 (25)/ 2020-11-04 (69)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682005; Age (years): 52; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Myalgia/ LEFT SHOULDER MUSCLE PAIN	2020-08-27 (4)/ 2020-08-29 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHES	2020-10-06 (16)/ 2020-10-26 (36)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3682019; Age (years): 43; Sex: F; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-25 (3)/ 2020-10-19 (27)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682036; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ BILATERAL ARM MUSCLE TENDERNESS	2020-09-11 (12)/ 2020-09-18 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ L ARM INJECTION PAIN	2020-09-12 (13)/ 2020-09-14 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3682077; Age (years): 66; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash macular/ MACULAR NON-URTICARIAL RASH, TORSO	2020-10-09 (3)/ 2020-10-11 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682095; Age (years): 75; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Depressed mood/ DEPRESSED MOOD	2020-10-10 (2)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Psychiatric disorders/ Insomnia/ INSOMNIA	2020-10-10 (2)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3682114; Age (years): 34; Sex: F; Race: MULTIPLE: (b) (6)							
Gastrointestinal disorders/ Diarrhoea/ INTERMITTENT DIARRHEA	2020-09-15 20:00 (1)/ 2020-09-20 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3682170; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ BILATERAL FOOT PAIN	2020-10-05 (8)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682170; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ BILATERAL HAND PAIN	2020-10-05 (8)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthralgia/ INTERMITTENT BILATERAL JOINT PAIN TO KNEES AND ELBOWS	2020-11-02 (8)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3682188; Age (years): 71; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-11 (8)/ 2020-11-11 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682188; Age (years): 71; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES OVER BODY	2020-11-11 (8)/ 2020-11-11 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692008; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Tenderness/ TENDERNESS, LEFT ARM	2020-08-29 (3)/ 2020-09-07 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692044; Age (years): 37; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE- LEFT. NON-URTICARIAL.	2020-09-30 09:42 (1)/ 2020-10-19 (20)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692044; Age (years): 37; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-10-01 (2)/ 2020-10-09 (10)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692053; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS, LEFT ARM	2020-09-11 (8)/ 2020-09-11 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site irritation/ INJECTION SITE IRRITATION, LEFT ARM	2020-09-11 (8)/ 2020-09-11 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692053; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site urticaria/ INJECTION SITE HIVES, LEFT ARM	2020-09-11 (8)/ 2020-09-11 (8)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692070; Age (years): 63; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT UNDERARM SWELLING, WALNUT SIZED, SOFT, NO PAIN, NO REDNESS. SAME SIDE AS VACCINE.	2020-09-20 (13)/ 2020-09-22 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-05 (28)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692087; Age (years): 39; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ LEFT ARM RASH (RED PATCHY THAT ITCHES AND FEELS HOT)	2020-09-16 (8)/ 2020-09-18 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692090; Age (years): 67; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RIGHT ARM RASH (95 MM). RED, ITCHY, AND SLIGHTLY RAISED.	2020-09-23 (14)/ 2020-09-26 (17)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692095; Age (years): 44; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-12 12:00 (1)/ 2020-09-18 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692123; Age (years): 36; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash macular/ RASH ON LEFT ARM -- NON-URTICARIAL, MACULAR.	2020-09-24 (9)/ 2020-09-30 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692157; Age (years): 49; Sex: F; Race: NOT REPORTED							
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 (1)/ Ongoing	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-25 (6)/ 2020-11-01 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692205; Age (years): 58; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMA- FACIAL AREA	2020-11-20 12:23 (1)/ 2020-11-20 13:30 (1)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702008; Age (years): 69; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-09-02 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3702010; Age (years): 74; Sex: M; Race: UNKNOWN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-04 (1)/ 2020-09-11 (8)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-05 20:22 (2)/ 2020-09-11 (8)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-11 (8)/ 2020-10-02 (29)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702013; Age (years): 67; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site rash/ RASH AT INJECTION SITE	2020-10-08 (1)/ 2020-10-10 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3702016; Age (years): 50; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHES (EDIARY)	2020-09-25 (5)/ 2020-09-30 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3702019; Age (years): 31; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site paraesthesia/ TINGLING SENSATION AT INJECTION SITE	2020-09-18 (1)/ 2020-10-28 (41)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702019; Age (years): 31; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT DELTOID (EDIARY)	2020-09-25 (8)/ 2020-09-29 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ ITCH AT INJECTION SITE (EDIARY)	2020-09-25 (8)/ 2020-09-29 (12)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3702024; Age (years): 72; Sex: M; Race: NOT REPORTED							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-14 (2)/ 2020-10-15 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702027; Age (years): 74; Sex: M; Race: WHITE							
Psychiatric disorders/ Nightmare/ NIGHTMARES	2020-10-10 03:00 (1)/ 2020-10-11 19:00 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3702052; Age (years): 30; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCH AT INJECTION SITE	2020-10-02 (1)/ 2020-10-11 (10)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3702093; Age (years): 41; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Feeling abnormal/ MENTALLY CLOUDY ("ZONED OUT")	2020-10-24 (2)/ 2020-10-25 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3712040; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT LEFT DELTOID INJECTION SITE	2020-09-19 (10)/ 2020-09-25 (16)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ ITCHY AT INJECTION SITE	2020-09-19 (10)/ 2020-09-25 (16)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT LEFT DELTOID INJECTION SITE	2020-09-19 (10)/ 2020-09-25 (16)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3712109; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-10-16 13:00 (1)/ 2020-11-06 10:00 (22)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3712118; Age (years): 43; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHY AT INJECTION SITE	2020-09-30 (9)/ 2020-10-02 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-10-01 (10)/ 2020-10-02 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3712251; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Injection site infection/ LEFT ARM INJECTION SITE INFECTION	2020-11-09 (18)/ 2020-11-10 (19)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722016; Age (years): 35; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-01 19:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3722055; Age (years): 43; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-03 19:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722065; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ SORENESS AT INJECTION SITE	2020-08-04 13:00 (1)/ 2020-08-06 23:00 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722134; Age (years): 61; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-04 08:00 (1)/ 2020-09-04 23:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722159; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-13 (4)/ 2020-08-17 (8)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722187; Age (years): 71; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-10 15:00 (30)/ 2020-09-10 22:00 (31)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN IN THE INJECTION SITE	2020-09-10 15:00 (30)/ 2020-09-10 23:00 (31)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722224; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722224; Age (years): 52; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722239; Age (years): 20; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pyrexia/ FEVER OF 101.4 DAY 1 AND 102.1 DAY 2	2020-09-10 17:00 (1)/ 2020-09-11 22:00 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722239; Age (years): 20; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-10 17:00 (1)/ 2020-09-11 22:00 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722268; Age (years): 37; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 08:00 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-09-16 08:00 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3722403; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-29 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722403; Age (years): 32; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-29 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-29 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ WORSENING HEADACHE	2020-09-29 (1)/ 2020-10-16 09:00 (17)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732027; Age (years): 33; Sex: M; Race: ASIAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-06 (3)/ 2020-09-07 (4)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732048; Age (years): 31; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-08 (1)/ 2020-09-17 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-08 (1)/ 2020-09-20 (13)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-09-09 (2)/ 2020-09-19 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732048; Age (years): 31; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-09 (2)/ 2020-09-19 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732093; Age (years): 39; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (1)/ 2020-09-23 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732100; Age (years): 76; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 (11)/ 2020-10-05 (13)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732100; Age (years): 76; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES (GENERAL)	2020-10-03 (11)/ 2020-10-05 (13)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732112; Age (years): 40; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-19 (2)/ 2020-09-26 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732127; Age (years): 42; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-25 (5)/ 2020-08-26 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732187; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-08-27 (2)/ 2020-09-03 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-24 (2)/ 2020-10-01 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732240; Age (years): 49; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 (2)/ 2020-10-09 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732240; Age (years): 49; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-09-30 20:44 (2)/ 2020-10-13 (15)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-09-30 20:44 (2)/ 2020-10-18 (20)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732243; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-09-07 (7)/ 2020-09-26 (26)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732243; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-09-29 (1)/ 2020-10-06 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732279; Age (years): 53; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINT	2020-10-02 (1)/ 2020-10-10 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732286; Age (years): 29; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 (1)/ 2020-10-24 (18)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732286; Age (years): 29; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-10-07 (1)/ 2020-10-24 (18)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-07 (1)/ 2020-10-24 (18)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-07 (1)/ 2020-10-24 (18)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732295; Age (years): 32; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 (1)/ 2020-09-16 (8)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732295; Age (years): 32; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ WORSENING NON-MIGRAINE HEADACHE	2020-09-10 (2)/ 2020-09-19 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732300; Age (years): 20; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-07 17:16 (1)/ 2020-10-15 10:51 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 17:16 (1)/ 2020-10-16 18:00 (10)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732311; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY AT INJECTION SITE	2020-09-18 (9)/ 2020-10-22 (43)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732325; Age (years): 35; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-21 (8)/ 2020-09-25 (12)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-12 18:23 (1)/ 2020-10-26 (15)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732327; Age (years): 40; Sex: M; Race: MULTIPLE:				(b) (6)			
Nervous system disorders/ Headache/ WORSENING NON-MIGRAINE HEADACHE	2020-10-12 (1)/ 2020-10-25 12:30 (13)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-13 (2)/ 2020-10-21 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732333; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT SITE OF INJECTION	2020-09-15 12:16 (1)/ 2020-09-15 16:00 (1)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732342; Age (years): 32; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ LEFT AXILLARY PRURITIS	2020-09-16 (2)/ 2020-10-23 (39)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732342; Age (years): 32; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ WORSENING NON-MIGRAINE HEADACHE	2020-09-17 (3)/ 2020-10-06 (22)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732360; Age (years): 52; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 (5)/ 2020-09-28 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732399; Age (years): 32; Sex: M; Race: ASIAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ INTERMITTENT LEFT UNDERARM GLAND DISCOMFORT/TENDERNESS	2020-10-19 (1)/ 2020-10-30 23:59 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732407; Age (years): 32; Sex: F; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-27 (5)/ 2020-10-31 (9)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742027; Age (years): 67; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ NIGHT TIME DIAPHORESIS	2020-08-24 (5)/ 2020-08-24 (5)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742072; Age (years): 49; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOL	2020-09-22 18:00 (1)/ 2020-09-23 18:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-22 19:09 (1)/ 2020-10-02 08:00 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Tendonitis/ LEFT ELBOW TENDONITIS	2020-09-23 08:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742072; Age (years): 49; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPING	2020-09-23 08:00 (1)/ 2020-09-23 18:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742088; Age (years): 55; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 12:06 (1)/ 2020-09-30 17:00 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-23 12:06 (1)/ 2020-10-03 08:00 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742089; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Vaccination site erythema/ REDNESS AT VACCINATION SITE	2020-09-24 (3)/ 2020-10-02 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Vaccination site pruritus/ PRUTITUS ON VACCINATION SITE	2020-09-24 (3)/ 2020-10-03 (12)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742089; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Vaccination site swelling/ SWELLING AT VACCINATION SITE	2020-09-24 (3)/ 2020-10-03 (12)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742092; Age (years): 69; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-27 (5)/ 2020-09-30 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742115; Age (years): 33; Sex: M; Race: WHITE							
Nervous system disorders/ Presyncope/ PRESYNCOPAL EPISODE	2020-09-26 18:00 (1)/ 2020-09-27 03:00 (1)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742138; Age (years): 33; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Bone pain/ LEFT CLAVICLE PAIN	2020-09-09 (13)/ 2020-09-09 (13)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Bone swelling/ LEFT CLAVICLE SWELLING	2020-09-26 01:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	
Subject ID: US3742150; Age (years): 54; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ PRURITUS AT INJECTION SITE	2020-09-28 (3)/ 2020-10-12 (17)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742167; Age (years): 34; Sex: M; Race: NOT REPORTED							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-01 09:07 (1)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-10-01 09:07 (1)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Axillary pain/ UNDERARM PAIN	2020-10-01 19:14 (1)/ 2020-10-11 11:00 (11)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE LEFT ARM	2020-10-01 19:14 (1)/ 2020-10-13 09:00 (13)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742167; Age (years): 34; Sex: M; Race: NOT REPORTED							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES [GENERALIZED]	2020-10-02 12:15 (2)/ 2020-10-12 09:00 (12)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 12:15 (2)/ 2020-10-14 02:00 (13)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES [GENERALIZED]	2020-10-02 12:15 (2)/ 2020-10-17 (17)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742169; Age (years): 57; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Rheumatoid arthritis/ RHEUMATOID ARTHRITIS	2020-08-31 23:00 (1)/ Ongoing	Yes/ Yes/ No	2	Yes/6	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742176; Age (years): 73; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-28 20:43 (1)/ 2020-10-07 (10)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ EXACERBATION OF RIGHT HIP PAIN	2020-10-02 (5)/ 2020-10-02 (5)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742180; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ RIGORS	2020-09-29 01:00 (1)/ 2020-09-29 04:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742208; Age (years): 22; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-05 (1)/ 2020-10-14 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 21:26 (1)/ 2020-10-14 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742211; Age (years): 71; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Vaccination site pain/ PAIN AT VACCINATION SITE (LEFT)	2020-09-30 21:07 (1)/ 2020-10-08 21:07 (9)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742224; Age (years): 57; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ L DELTOID PRURITUS	2020-09-10 (8)/ 2020-09-13 (11)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash erythematous/ NON-URTICARIAL LOCALIZED ERYTHEMIC RASH LATERAL TO VACCINATION SITE	2020-09-10 (8)/ 2020-09-13 (11)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742229; Age (years): 71; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ DIAPHORESIS	2020-09-30 16:00 (1)/ 2020-10-01 (2)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742277; Age (years): 68; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPING	2020-09-09 17:30 (2)/ 2020-09-09 17:31 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOL	2020-09-09 17:30 (2)/ 2020-09-09 17:31 (2)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPING	2020-09-11 (4)/ 2020-09-11 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742277; Age (years): 68; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOL	2020-09-11 (4)/ 2020-09-11 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742283; Age (years): 52; Sex: M; Race: NOT REPORTED							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ BODY ACHES (SHOULDERS)	2020-10-18 (14)/ 2020-10-20 (16)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN (LEFT) SUPRACLAVICULAR LYMPH NODES	2020-10-18 (14)/ 2020-11-03 (30)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742295; Age (years): 53; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ ARM JOINT PAIN	2020-09-17 (9)/ 2020-09-27 (19)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	2020-10-09 (2)/ 2020-10-16 (9)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-09 (2)/ 2020-10-16 (9)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742295; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-12 (5)/ 2020-10-15 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742307; Age (years): 20; Sex: F; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Skin burning sensation/ BURNING SENSATION OF SKIN	2020-10-06 21:41 (1)/ 2020-10-07 08:00 (1)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742308; Age (years): 56; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOLS	2020-10-10 (3)/ 2020-10-11 (4)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742311; Age (years): 65; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ INTERMITTENT PAIN AT LEFT TRICEP	2020-09-25 (16)/ 2020-10-16 (37)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742315; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-11 12:05 (1)/ 2020-09-19 13:21 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742326; Age (years): 42; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Axillary pain/ LEFT UNDERARM TENDERNESS	2020-10-12 (26)/ 2020-10-18 (32)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742328; Age (years): 34; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Axillary pain/ TENDERNESS LEFT ARMPIT	2020-10-11 (4)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3742332; Age (years): 72; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-10-09 00:28 (1)/ 2020-10-16 12:01 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-09 00:28 (1)/ 2020-10-16 12:01 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742335; Age (years): 52; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-10-08 (1)/ 2020-10-15 (8)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-10-08 (1)/ 2020-10-15 (8)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-09 (2)/ 2020-10-15 (8)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-09 (2)/ 2020-10-16 (9)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742344; Age (years): 71; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-10-08 22:36 (1)/ 2020-10-23 (16)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742367; Age (years): 29; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-12 16:41 (1)/ 2020-10-19 21:32 (8)	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742385; Age (years): 39; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN IN LEFT ARM	2020-09-24 (9)/ 2020-09-30 (15)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742385; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Vaccination site erythema/ ERYTHEMA AT VACCINATION 1 SITE	2020-09-25 (10)/ 2020-09-30 (15)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Vaccination site induration/ INDURATION AT VACCINATION 1 SITE	2020-09-25 (10)/ 2020-09-30 (15)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742385; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Vaccination site swelling/ SWELLING AT VACCINATION SITE	2020-10-13 15:00 (1)/ 2020-10-21 22:00 (9)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742393; Age (years): 31; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-18 (5)/ 2020-10-22 (9)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742396; Age (years): 58; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT NECK LYMPHADENEUROPATHY	2020-10-16 (3)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742401; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Angina pectoris/ CARDIAC CHEST PAIN	2020-09-23 (3)/ 2020-09-24 (4)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742411; Age (years): 53; Sex: F; Race: NOT REPORTED							
Nervous system disorders/ Headache/ HEADACHE	2020-10-01 20:30 (1)/ 2020-10-22 (22)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-05 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE LEFT ARM	2020-11-05 17:28 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742411; Age (years): 53; Sex: F; Race: NOT REPORTED							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-11-05 17:29 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-11-05 17:29 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT ARM	2020-11-06 15:51 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742411; Age (years): 53; Sex: F; Race: NOT REPORTED							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT THE INJECTION SITE LEFT ARM	2020-11-06 15:51 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Chills/ CHILLS	2020-11-12 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3742422; Age (years): 42; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT PAIN	2020-10-18 05:00 (1)/ 2020-10-26 (10)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742422; Age (years): 42; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-18 05:00 (1)/ 2020-10-26 (10)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742429; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Axillary pain/ IPSILATERAL LEFT UNDERARM TENDERNESS	2020-09-25 (7)/ 2020-09-30 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-18 (2)/ 2020-10-25 (9)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742431; Age (years): 20; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck mass/ LUMP ON LEFT SIDE OF NECK	2020-10-25 (9)/ 2020-11-14 (29)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742433; Age (years): 28; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-10-18 13:58 (1)/ 2020-10-25 (9)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-20 (4)/ 2020-10-27 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742438; Age (years): 53; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenitis/ LEFT UNDERARM GLAND SWOLLEN	2020-10-18 02:00 (1)/ 2020-10-27 (11)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-18 02:00 (1)/ 2020-10-27 (11)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742439; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Vaccination site rash/ RASH ON LEFT ARM AT VACCINATION SITE	2020-10-21 (5)/ 2020-10-23 (7)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742450; Age (years): 63; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ PAIN AT THE INJECTION SITE RIGHT ARM	2020-10-23 21:34 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742453; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT UNDER ARM GLAND SWELLING IPSILATERAL	2020-09-22 (1)/ 2020-10-04 (13)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742482; Age (years): 52; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT SWOLLEN UNDERARM GLAND IPSILATERAL	2020-10-06 (6)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742482; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-08 (8)/ 2020-10-12 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Mental impairment/ MENTAL FOG	2020-10-29 22:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-29 22:03 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3752006; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-07 (1)/ 2020-08-20 (14)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752010; Age (years): 67; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Swollen tongue/ SWOLLEN TONGUE WITH UNUSUAL SENSATIONS	2020-09-09 (2)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHES STATUS POST 2ND INJECTION	2020-09-12 (5)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3752024; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-14 (1)/ 2020-09-23 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752034; Age (years): 60; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-11 (2)/ 2020-09-17 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752046; Age (years): 38; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-10 (2)/ 2020-09-17 (9)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752049; Age (years): 37; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-08 (1)/ 2020-09-16 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752056; Age (years): 44; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Chills/ CHILLS	/ 2020-09-13 (33)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752070; Age (years): 69; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-10 (1)/ 2020-09-21 (12)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752082; Age (years): 34; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-13 (4)/ 2020-09-25 (16)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752086; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-12 (2)/ 2020-09-18 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752087; Age (years): 44; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY LYMPHADENOPATHY (LATERALITY UNKNOWN)	2020-08-19 (6)/ 2020-08-23 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hot flush/ HOT FLASHES	2020-09-11 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752087; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT ARM (UNKNOWN IF URTICARIAL OR NONURTICARIAL)	2020-09-13 (3)/ 2020-09-18 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752129; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-21 (1)/ 2020-10-02 (12)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752133; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-19 (2)/ 2020-08-26 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752133; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-24 (7)/ 2020-08-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752142; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-19 (2)/ 2020-09-08 (22)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752143; Age (years): 37; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINTS ACHE (LOCATION UNKNOWN)	2020-08-25 (7)/ 2020-08-27 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752153; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS (UNKNOWN LOCATION)	2020-08-20 (2)/ 2020-08-29 (11)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ LEFT ARM INJECTION SITE REDNESS (TYPE OF REDNESS UNKNOWN AND UNKNOWN IF URTICARIAL OR NONURTICARIAL)	2020-09-17 (2)/ 2020-09-25 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752153; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ LEFT ARM INJECTION SITE INDURATION	2020-09-17 (2)/ 2020-09-25 (10)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ LEFT ARM INJECTION SITE PAIN	2020-09-17 (2)/ 2020-09-25 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ LEFT ARM INJECTION SITE SWELLING	2020-09-17 (2)/ 2020-09-25 (10)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752156; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-19 (1)/ 2020-09-01 (14)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ LOW GRADE FEVER	2020-09-15 00:00 (27)/ 2020-09-16 00:00 (28)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Malaise/ MALAISE	2020-09-16 00:00 (1)/ 2020-09-16 00:01 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752159; Age (years): 35; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY GLAND LYMPHADENOPATHY (LATERALITY UNKNOWN)	2020-08-21 (3)/ 2020-08-30 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-16 (1)/ 2020-10-21 (36)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (1)/ 2020-10-21 (36)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752159; Age (years): 35; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-16 (1)/ 2020-10-21 (36)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-16 (1)/ 2020-10-21 (36)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-16 (1)/ 2020-10-21 (36)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752163; Age (years): 61; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES (LOCATION UNKNOWN)	2020-08-21 (3)/ 2020-08-27 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (LOCATION UNKNOWN)	2020-08-21 (3)/ 2020-08-28 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752172; Age (years): 35; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ MILD TO MODERATE ANXIETY	2020-09-16 (2)/ 2020-09-18 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752183; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 (7)/ 2020-08-30 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752189; Age (years): 28; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE	2020-09-16 (1)/ 2020-10-01 (16)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-17 (2)/ 2020-09-28 (13)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752190; Age (years): 47; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING	2020-08-25 (6)/ 2020-08-29 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752195; Age (years): 20; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-21 (1)/ 2020-08-29 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE LYMPHADENOPATHY UNDERARM GLAND ON THE LEFT	2020-08-26 (6)/ 2020-08-29 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752195; Age (years): 20; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-26 (6)/ 2020-08-29 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHE	2020-08-27 (7)/ 2020-08-29 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752202; Age (years): 69; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ LEFT ARM REDNESS (TYPE AND IF URTICARIAL OR NOT UNKNOWN	2020-08-30 (10)/ 2020-09-02 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752202; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS RIGHT ARM INJECTION SITE (TYPE AND IF URTICARIAL OR NOT UNKNOWN)	2020-09-20 (3)/ 2020-09-25 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN RIGHT ARM INJECTION SITE	2020-09-20 (3)/ 2020-09-25 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752206; Age (years): 72; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-23 (3)/ 2020-09-01 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752207; Age (years): 51; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-21 (1)/ 2020-09-05 (16)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ SUPRACLAVICULAR GLAND SWELLING	2020-09-19 (2)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752329; Age (years): 35; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-02 (2)/ 2020-09-09 (9)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752332; Age (years): 50; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-05 (5)/ 2020-10-11 (11)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752393; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS LEFT ARM INJECTION SITE 8 CM X 5 CM	2020-09-11 (9)/ 2020-09-14 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ SWELLING LEFT ARM INJECTION SITE 8 CM X 5 CM	2020-09-11 (9)/ 2020-09-14 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752402; Age (years): 70; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-07 (4)/ 2020-09-14 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762063; Age (years): 80; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS LEFT ARM	2020-09-06 (12)/ 2020-09-09 (15)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3762074; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-04 (9)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3762140; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ RASH FROM INJECTION SITE TO ELBOW NON-URTICARIAL	2020-09-12 (12)/ 2020-09-16 (16)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762159; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-09-17 (16)/ 2020-09-19 (18)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Tenderness/ TENDERNESS	2020-09-17 (16)/ 2020-09-19 (18)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Skin warm/ WARM TO TOUCH	2020-09-17 (16)/ 2020-09-19 (18)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762165; Age (years): 41; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-05 (3)/ 2020-09-05 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3762175; Age (years): 81; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT AXILLARY LYMPHADENOPATHY	2020-09-04 00:00 (1)/ 2020-09-05 23:59 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3762177; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-04 00:00 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762177; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ INTERMITTENT BODY ACHES	2020-09-04 00:00 (1)/ Ongoing	Yes/ No/ No	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Abdominal pain upper/ STOMACH ACHE	2020-09-13 (11)/ Ongoing	Yes/ No/ No	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING
Subject ID: US3772017; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-20 (13)/ 2020-09-22 (15)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772021; Age (years): 67; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 13:00 (1)/ 2020-10-14 14:00 (36)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772046; Age (years): 82; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-08-20 (10)/ 2020-08-21 (11)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772057; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-18 (6)/ 2020-08-22 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA ALL OVER BODY	2020-08-18 (6)/ 2020-08-23 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772057; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERAL ARTHRALGIA	2020-08-19 (7)/ 2020-08-20 (8)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-19 (7)/ 2020-08-21 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site induration/ INDURATION AT INJECTION SITE	2020-08-21 (9)/ 2020-08-22 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772057; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-21 (9)/ 2020-08-22 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772069; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-15 (2)/ 2020-08-23 (10)	Yes/ No/ Yes	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-08-16 (3)/ 2020-08-23 (10)	Yes/ No/ Yes	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772069; Age (years): 58; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-08-16 (3)/ 2020-08-23 (10)	Yes/ No/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772076; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-19 (4)/ 2020-09-24 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 (4)/ 2020-09-24 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-09-21 (6)/ 2020-09-24 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772078; Age (years): 78; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-18 (2)/ 2020-08-24 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-08-18 (2)/ 2020-08-26 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772087; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-18 (1)/ 2020-08-26 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772087; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-14 (1)/ 2020-09-23 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-15 (2)/ 2020-09-25 (12)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-09-15 (2)/ 2020-09-25 (12)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772087; Age (years): 55; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-15 (2)/ 2020-09-25 (12)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772098; Age (years): 58; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY LYMPHADENOPATHY IPSILATERAL	2020-09-18 (2)/ 2020-09-24 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-18 (2)/ 2020-09-24 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772098; Age (years): 58; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA MULTIPLE JOINTS	2020-09-18 (2)/ 2020-09-24 (8)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772126; Age (years): 40; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-23 (3)/ 2020-09-02 (13)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-23 (3)/ 2020-09-03 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772133; Age (years): 60; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-26 (5)/ 2020-08-30 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772148; Age (years): 50; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS	2020-09-28 (7)/ 2020-10-05 (14)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772163; Age (years): 56; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-28 (1)/ 2020-09-04 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-29 (2)/ 2020-09-05 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772165; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-26 08:30 (1)/ 2020-10-02 19:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772180; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-25 22:17 (1)/ 2020-10-03 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772195; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-06 (7)/ 2020-10-08 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772196; Age (years): 46; Sex: F; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL LYMPHADENOPATHY	2020-09-29 (2)/ 2020-10-10 (13)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772266; Age (years): 31; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-16 (5)/ 2020-09-24 (13)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782026; Age (years): 30; Sex: M; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADED	2020-09-15 10:00 (1)/ 2020-09-15 10:15 (1)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3782070; Age (years): 61; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 (7)/ 2020-09-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3782086; Age (years): 53; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA LEFT ARM	2020-09-02 (9)/ 2020-09-04 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782111; Age (years): 44; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site swelling/ DIFFUSE, IMMEASURABLE SWELLING AT INJECTION SITE	2020-09-05 (9)/ 2020-09-06 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Vaccination site lymphadenopathy/ TENDER, 1CM, LEFT INFRACLAVICULAR LYMPHADENOPATHY IPSILATERAL TO VACCINATION ARM	2020-09-06 (10)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782141; Age (years): 38; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIAS	2020-10-07 (7)/ 2020-10-09 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782157; Age (years): 47; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT SUPRACLAVICULAR LYMPHADENOPATHY	2020-09-09 18:45 (2)/ 2020-09-14 08:00 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT SUPRACLAVICULAR LYMPHADENOPATHY	2020-10-06 03:00 (1)/ 2020-10-09 20:47 (5)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782176; Age (years): 30; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-13 (8)/ 2020-10-14 (9)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-13 (8)/ 2020-10-15 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-13 (8)/ 2020-10-15 (10)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782179; Age (years): 43; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Vaccination site erythema/ NON-URTICARIAL ERYTHEMA AT STUDY VACCINE SITE LEFT ARM	2020-10-16 (8)/ 2020-10-19 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802026; Age (years): 36; Sex: F; Race: WHITE							
Vascular disorders/ Flushing/ TRANSIENT FLUSHING UPPER BODY	2020-09-20 (28)/ 2020-09-20 (28)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dysgeusia/ METALLIC TASTE ON TONGUE	2020-09-23 21:00 (2)/ 2020-09-25 09:00 (3)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802028; Age (years): 26; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dyspepsia/ INDIGESTION	2020-09-14 (21)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3802054; Age (years): 44; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Menorrhagia/ HEAVY AND PROLONGED MENSTRUATION	2020-09-27 (5)/ 2020-10-02 (10)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802056; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHES	2020-10-01 (9)/ 2020-10-03 (11)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802082; Age (years): 32; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-28 15:00 (1)/ 2020-10-05 17:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802085; Age (years): 57; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pityriasis rosea/ PITYRIASIS ROSEA	2020-09-26 08:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3802094; Age (years): 73; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ REDNESS LEFT DELTOID	2020-09-11 (11)/ 2020-09-12 (12)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ PRURITIS LEFT ARM INJECTION SITE	2020-09-30 (3)/ 2020-10-04 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802097; Age (years): 26; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADANOPATHY LEFT SIDED SUBMENTAL NODES	2020-09-06 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802097; Age (years): 26; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY LEFT SUPRACLAVICULAR NODE	2020-09-06 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3802104; Age (years): 61; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE SORENESS	2020-10-01 06:00 (1)/ 2020-10-02 06:00 (2)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802108; Age (years): 76; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ PRURITIS DISTAL INJECTION SITE	2020-09-30 (2)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802108; Age (years): 76; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-30 (2)/ 2020-10-01 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site rash/ RASH DISTAL INJECTION SITE	2020-10-06 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Skin hypopigmentation/ HYPOPIGMENTATION UPPER ARM	2020-10-28 (30)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802113; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-16 (15)/ 2020-09-18 (17)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3802136; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-10-03 (2)/ 2020-10-06 (5)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802143; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Malaise/ IMMEDIATE SENSE OF UNWELL	2020-10-07 09:15 (1)/ 2020-10-07 09:30 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802143; Age (years): 53; Sex: M; Race: WHITE							
Psychiatric disorders/ Affect lability/ EMOTIONAL INSTABILITY	2020-10-10 (4)/ 2020-10-12 (6)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802148; Age (years): 53; Sex: F; Race: WHITE							
Vascular disorders/ Hot flush/ HOT FLASHES	2020-09-28 (22)/ 2020-09-28 (22)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802186; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ BELOW INJECTION SITE ERYTHEMA	2020-09-18 (10)/ 2020-09-27 (19)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ HIVES	2020-09-23 (15)/ 2020-10-07 (29)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802186; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-09 (3)/ 2020-10-30 (24)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802232; Age (years): 31; Sex: F; Race: ASIAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-09-24 (11)/ 2020-09-26 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802245; Age (years): 27; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADANOPATHY LEFT CLAVICULAR NODE, IPSILATERAL	2020-09-20 (7)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3802257; Age (years): 38; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ PARESTHESIA LEFT ARM	2020-09-15 16:00 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812006; Age (years): 69; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES-GENERALIZED	2020-09-01 (1)/ 2020-09-13 (13)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES-GENERALIZED	2020-09-01 (1)/ 2020-09-13 (13)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-03 (3)/ 2020-09-13 (13)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812010; Age (years): 71; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash maculo-papular/ NON-URTICARIAL MACULOPAPULAR RASH TO LEFT UPPER ARM (BELOW INJECTION SITE)	2020-08-12 (10)/ 2020-08-14 (12)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812022; Age (years): 70; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ RASH LEFT UPPER ARM [WHEAL]-URTICARIAL	2020-08-12 (9)/ 2020-08-16 (13)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ RASH LEFT UPPER ARM [WHEAL]-URTICARIAL	2020-09-01 11:00 (1)/ 2020-09-06 22:00 (7)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812022; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site haemorrhage/ INJECTION SITE ECCHYMOSIS	2020-09-01 11:00 (1)/ 2020-09-12 22:00 (13)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812071; Age (years): 70; Sex: F; Race: WHITE							
Nervous system disorders/ Cervical radiculopathy/ INTERMITTENT NERVE PAIN NECK	2020-09-02 02:00 (1)/ 2020-09-02 07:00 (1)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812132; Age (years): 72; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS ON LEFT ARM	2020-09-09 09:00 (1)/ 2020-09-17 09:00 (9)	Yes/ Yes/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812149; Age (years): 41; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY (IPSILATERAL)	2020-09-10 (2)/ 2020-09-22 14:00 (14)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812158; Age (years): 38; Sex: M; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Dermatitis/ GENERALIZED DERMATITIS	2020-09-12 (3)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812179; Age (years): 34; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-08-17 (3)/ 2020-08-27 (13)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812205; Age (years): 71; Sex: F; Race: WHITE							
Nervous system disorders/ Balance disorder/ UNSTEADINESS	2020-08-23 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812205; Age (years): 71; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo positional/ BENIGN PAROXYSMAL POSITIONAL VERTIGO	2020-08-23 (6)/ 2020-09-12 (26)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE (RELATED TO BENIGN PAROXYSMAL POSITIONAL VERTIGO)	2020-08-23 (6)/ 2020-09-12 (26)	Yes/ Yes/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812236; Age (years): 50; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	2020-09-19 00:00 (1)/ 2020-10-18 (31)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812236; Age (years): 50; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Abnormal loss of weight/ UNINTENTIONAL WEIGHT LOSS (DOWN 6 LBS)	2020-10-02 (15)/ 2020-10-18 (31)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812253; Age (years): 53; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ PARESTHSIA L ARM	2020-08-24 13:30 (1)/ 2020-08-27 (4)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812294; Age (years): 27; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Swelling/ UNDERARM SWELLING	2020-09-04 (8)/ 2020-09-07 (11)	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812301; Age (years): 41; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-28 06:30 (31)/ 2020-10-07 (41)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812301; Age (years): 41; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-28 06:30 (31)/ 2020-10-07 (41)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812318; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-10-02 (1)/ 2020-10-12 (11)	Yes/ Yes/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-03 02:00 (1)/ 2020-10-03 02:01 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Neck pain/ ACUTE NECK PAIN	2020-10-07 (6)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812318; Age (years): 61; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus pain/ SINUS PAIN	2020-10-07 (6)/ 2020-10-09 (8)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812320; Age (years): 56; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-10-09 19:00 (1)/ 2020-10-26 07:30 (17)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812344; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-26 (2)/ 2020-09-29 (5)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812344; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chest discomfort/ INTERMITTENT CHEST TIGHTNESS WITHOUT SHORTNESS OF BREATH	2020-09-26 (2)/ 2020-10-09 (15)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Musculoskeletal stiffness/ INTERMITTENT NECK STIFFNESS	2020-09-26 (2)/ 2020-10-20 05:30 (25)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822001; Age (years): 60; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ AXILLARY LYMPHADENOPATHY, LEFT ARM (SAME SIDE AS VACCINATION SITE)	2020-08-10 11:00 (7)/ 2020-08-15 11:00 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822014; Age (years): 80; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-01 18:00 (1)/ 2020-09-09 00:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822020; Age (years): 65; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ DULL ACHE IN LOWER EXTREMITIES	2020-09-01 00:00 (1)/ 2020-09-04 12:00 (4)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822030; Age (years): 73; Sex: F; Race: WHITE							
Eye disorders/ Eye irritation/ BURNING EYES	2020-08-06 18:00 (1)/ 2020-08-07 00:00 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: USED REFRESH EYE DROPS
Vascular disorders/ Hot flush/ WORSENING OF HOT FLASHES	2020-09-02 00:00 (27)/ Ongoing	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3822034; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-03 08:30 (1)/ 2020-09-04 12:00 (2)	Yes/ No/ No	1	No	R/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822036; Age (years): 32; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-04 06:30 (28)/ Ongoing	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822043; Age (years): 75; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ ENLARGED LEFT AXILLARY LYMPH NODES	2020-09-05 (4)/ 2020-10-06 (35)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ B-cell small lymphocytic lymphoma/ SMALL LYMPHOCYTIC LYMPHOMA	2020-10-06 11:00 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/6	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822044; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling/ UNDERARM SWELLING	2020-08-08 (2)/ 2020-08-31 (25)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822066; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-15 (2)/ 2020-09-22 (9)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822074; Age (years): 37; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Temporomandibular joint syndrome/ TMJ EXACERBATION	2020-08-12 (2)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Ear infection/ EAR INFECTION	2020-08-15 (5)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822087; Age (years): 48; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 (17)/ Ongoing	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822121; Age (years): 73; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-09-18 (1)/ 2020-09-27 (10)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-18 (1)/ 2020-09-27 (10)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822129; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE CRAMP	2020-08-19 (6)/ 2020-08-20 (7)	Yes/ No/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: PT TOOK TYLENOL
Subject ID: US3822134; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-14 13:00 (1)/ 2020-08-24 12:00 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822138; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-14 (1)/ 2020-08-22 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822146; Age (years): 45; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA, GENERALIZED	2020-08-17 13:30 (1)/ 2020-08-25 00:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822146; Age (years): 45; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA, GENERALIZED	2020-08-17 13:45 (1)/ 2020-08-25 00:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-17 14:00 (1)/ 2020-08-25 00:00 (8)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822150; Age (years): 67; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPS	2020-08-23 (7)/ 2020-08-23 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-23 (7)/ 2020-08-23 (7)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822151; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA	2020-08-31 (15)/ 2020-09-07 (22)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822177; Age (years): 64; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-19 17:00 (2)/ 2020-08-25 23:59 (8)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822186; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 00:00 (36)/ 2020-10-01 07:00 (43)	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-01 (8)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822258; Age (years): 55; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY - SAME SIDE OF VACCICATION SITE	2020-09-01 (8)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3822310; Age (years): 45; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bone lesion/ LUMP ON TOP OF COLLARBONE	2020-09-06 (10)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3822405; Age (years): 35; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 (6)/ 2020-09-25 (9)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822415; Age (years): 26; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-21 20:30 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-21 22:15 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822420; Age (years): 39; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 00:00 (3)/ 2020-09-25 15:00 (4)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822425; Age (years): 63; Sex: M; Race: UNKNOWN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-24 00:00 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832089; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Vaccination site lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY (IPSILATERAL-SAME SIDE OF VACCINATION)	2020-09-02 19:36 (2)/ 2020-09-15 00:00 (14)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852036; Age (years): 53; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dry mouth/ DRY MOUTH	2020-09-29 22:00 (1)/ 2020-09-30 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-09-29 23:59 (1)/ 2020-09-30 (2)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852042; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTION SITE	2020-09-06 (11)/ 2020-09-10 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852067; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING @ INJECTION SITE	2020-09-12 (13)/ 2020-09-20 (21)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852073; Age (years): 42; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bone pain/ LEFT SIDED COLLARBONE TENDERNESS/PAIN	2020-10-01 (3)/ 2020-10-05 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852073; Age (years): 42; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ LEFT SIDED NECK PAIN/TENDERNESS	2020-10-01 (3)/ 2020-10-05 (7)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852081; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT THE INJECTION SITE	2020-09-04 (4)/ 2020-09-05 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site irritation/ IRRITATION @ INJECTION SITE	2020-09-13 (13)/ 2020-09-15 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852119; Age (years): 66; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ UNDERARM GLAND ITCHING	2020-10-09 07:00 (1)/ 2020-10-13 07:00 (5)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3862028; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ IPSILATERAL INJECTION SITE - LYMPHADENOPATHY	2020-09-16 09:00 (1)/ 2020-09-22 13:35 (7)	Yes/ No/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862035; Age (years): 62; Sex: F; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL - LEFT AXILLARY LYMPADENOPATHY NOTED ON ULTRASOUND	2020-09-30 (17)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862037; Age (years): 80; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RESIDUAL ERYTHEMA ON INJECTION SITE	2020-09-17 13:18 (1)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862084; Age (years): 57; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL - LEFT SUPRACLAVICULAR LYMPHADENOPATHY	2020-09-26 08:00 (1)/ 2020-10-14 09:00 (19)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3862085; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA IN HANDS	2020-08-28 21:00 (1)/ 2020-09-06 (10)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862121; Age (years): 60; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ TENDERNESS AT INJECTION SITE	2020-09-14 (12)/ 2020-09-15 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3862125; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site irritation/ INJECTION SITE REACTION IRRITATION	2020-09-09 (7)/ 2020-09-20 (18)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3862152; Age (years): 53; Sex: F; Race: NOT REPORTED							
Blood and lymphatic system disorders/ Lymphadenopathy/ INJECTION SITE AXILLARY LYMPHADENOPATHY	2020-09-15 (7)/ 2020-09-21 (13)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862175; Age (years): 51; Sex: F; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash pruritic/ RASH [ERYTHEMATOUS AND PRURITIC] OF VACCINATED ARM	2020-09-13 (3)/ 2020-10-02 (22)	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL AXILLARY LYMPHADENOPATHY	2020-09-17 (7)/ 2020-09-25 (15)	Yes/ No/ Yes	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3862181; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE FOR 6 HOURS	2020-09-28 (15)/ 2020-09-28 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862285; Age (years): 61; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH	2020-10-17 (3)/ 2020-10-19 (5)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872130; Age (years): 76; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-12 (5)/ 2020-10-12 (35)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES-GENERALIZED	2020-09-12 (5)/ 2020-10-12 (35)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872167; Age (years): 75; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-15 16:30 (1)/ 2020-10-14 08:00 (29)	Yes/ No/ Yes	2	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF JOINT PAIN IN HIPS AND KNEES	2020-09-15 16:30 (1)/ 2020-10-14 08:00 (29)	Yes/ No/ Yes	2	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872198; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE 5CMX5CM	2020-08-24 (11)/ 2020-08-26 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872198; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site mass/ SMALL BUMP AT INJECTION SITE 1CM	2020-08-24 (11)/ 2020-08-26 (13)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3872217; Age (years): 75; Sex: F; Race: WHITE							
Vascular disorders/ Hot flush/ HOT FLASHES	2020-09-16 18:00 (1)/ 2020-09-19 00:00 (3)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3872248; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 (20)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3872262; Age (years): 44; Sex: M; Race: WHITE							
Vascular disorders/ Hot flush/ HOT FLASHES	2020-09-30 00:00 (1)/ 2020-10-14 00:00 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872272; Age (years): 50; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Axillary pain/ LEFT AXILLARY TENDERNESS	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site induration/ INJECTION SITE INDURATION	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872272; Age (years): 50; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE TENDERNESS	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site warmth/ INJECTION SITE WARMTH	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Joint range of motion decreased/ LEFT UPPER ARM LIMITED RANGE OF MOTION	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872372; Age (years): 47; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Tinnitus/ TINNITUS	2020-10-10 (2)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ HIVES	2020-10-20 (12)/ 2020-10-23 (15)	Yes/ No/ No	1	No	R/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872440; Age (years): 35; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT SIDED AXILLARY SWELLING (LYMPHADENOPATHY) SAME SIDE AS VACCINE	2020-09-09 (7)/ 2020-09-13 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872440; Age (years): 35; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ RIGHT SIDED SWELLING AT INJECTION SITE	2020-09-09 (7)/ 2020-09-13 (11)	Yes/ No/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site rash/ RIGHT ARM RASH AT INJECTION SITE RIGHT ARM NON URTICARIAL	2020-09-11 (9)/ 2020-09-13 (11)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872456; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT DELTOID	2020-09-13 (10)/ 2020-09-14 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872456; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE LEFT DELTOID	2020-09-13 (10)/ 2020-09-14 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3872474; Age (years): 33; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT DELTIOD. NON URTICARIAL	2020-09-16 (9)/ 2020-09-21 (14)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3872480; Age (years): 35; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 20:16 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3882015; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-05 (4)/ 2020-10-05 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHE	2020-10-05 (4)/ 2020-10-05 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 (4)/ 2020-10-05 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3882019; Age (years): 74; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-09 (1)/ 2020-09-09 (1)	Yes/ No/ No	1	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3882043; Age (years): 42; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHE	2020-11-12 (1)/ Ongoing	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Pyrexia/ HIGH TEMPERATURE	2020-11-12 (1)/ 2020-11-12 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3882070; Age (years): 45; Sex: M; Race: ASIAN							
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOL	2020-11-06 (15)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-11-10 (19)/ 2020-11-12 (21)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3892026; Age (years): 55; Sex: M; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-09-26 10:00 (1)/ 2020-09-26 22:00 (2)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3892081; Age (years): 36; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-22 (9)/ 2020-09-26 (13)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash papular/ ERYTHEMA LEFT ARM, PAPULAR, CONFLUENT, NON-URTICARIAL	2020-09-22 (9)/ 2020-09-26 (13)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3902016; Age (years): 77; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES ON LEFT THIGH	2020-09-08 (7)/ 2020-09-20 (19)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3902030; Age (years): 66; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Lip swelling/ SWOLLEN LIPS	2020-09-05 (3)/ 2020-09-08 (6)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ HIVES	2020-09-05 (3)/ 2020-09-21 (19)	Yes/ Yes/ No	1	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ SORE HANDS	2020-09-05 (3)/ 2020-09-23 (21)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3902041; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest discomfort/ TIGHTNESS IN CHEST	2020-10-12 18:00 (1)/ 2020-10-15 (4)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-12 18:00 (1)/ 2020-10-15 (4)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3902075; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site haemorrhage/ ECCHYMOSIS @ INJECTION SITE	2020-09-11 18:30 (1)/ 2020-09-12 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912003; Age (years): 75; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-25 18:20 (1)/ 2020-08-25 18:39 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912029; Age (years): 76; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-08-31 (4)/ 2020-09-05 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912033; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING NEAR INJECTION SITE	2020-09-06 (9)/ 2020-09-08 (11)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912034; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-29 (1)/ 2020-09-14 (17)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE LEFT ARM	2020-09-28 (1)/ 2020-10-07 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912042; Age (years): 60; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-28 21:30 (1)/ 2020-09-29 07:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-28 21:30 (1)/ 2020-09-29 07:00 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912056; Age (years): 70; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-31 17:45 (1)/ 2020-08-31 21:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912086; Age (years): 68; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Joint range of motion decreased/ LIMITED RANGE OF MOTION, RIGHT ARM	2020-09-16 (15)/ 2020-09-30 (29)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912110; Age (years): 47; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ MILD ITCHING AT INJECTION SITE	2020-09-15 (12)/ 2020-09-17 (14)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912113; Age (years): 32; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-09 (8)/ 2020-10-10 (9)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912114; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION LEFT DELTOID (ITCHING)	2020-09-13 (10)/ 2020-09-18 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912116; Age (years): 58; Sex: M; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash/ RASH ON INSIDE OF LEFT ARM	2020-09-07 (4)/ 2020-09-22 (19)	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912116; Age (years): 58; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS-BILATERAL UPPER EXTREMITIES	2020-10-03 (2)/ Ongoing	Yes/ Yes/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-03 12:02 (1)/ 2020-10-12 12:03 (10)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-03 12:02 (1)/ 2020-10-12 12:03 (10)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912128; Age (years): 49; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-14 (7)/ 2020-09-18 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912130; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION GRADE 3	2020-09-08 16:36 (1)/ 2020-09-09 10:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912156; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-09 (1)/ 2020-10-18 (10)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912165; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-20 (6)/ 2020-09-25 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912165; Age (years): 56; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-21 (7)/ 2020-09-25 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-21 (7)/ 2020-09-25 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-21 (7)/ 2020-09-27 (13)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-14 08:00 (1)/ 2020-10-15 08:30 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912166; Age (years): 23; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Menorrhagia/ MENORRHAGIA	2020-09-16 (2)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912185; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-24 (7)/ 2020-09-26 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912194; Age (years): 34; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REACTION-ERYTHEMA	2020-09-28 (10)/ 2020-09-30 (12)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912197; Age (years): 52; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-21 19:23 (1)/ 2020-09-30 12:00 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912200; Age (years): 46; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION GRADE 3	2020-09-22 15:28 (1)/ 2020-09-22 15:54 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912205; Age (years): 47; Sex: M; Race: ASIAN							
Nervous system disorders/ Disturbance in attention/ DIFFICULTY CONCENTRATING	2020-10-22 09:00 (1)/ 2020-11-04 (15)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3922084; Age (years): 42; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	2020-10-18 (10)/ 2020-10-25 (17)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3922127; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Peripheral swelling/ SWELLING OF LEFT FOREARM	2020-10-23 (2)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932004; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-31 18:24 (1)/ 2020-09-08 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-29 18:03 (1)/ 2020-10-09 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 18:03 (1)/ 2020-10-09 (11)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932004; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-01 (3)/ 2020-10-09 (11)	Yes/ No/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932008; Age (years): 76; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ BODY RASH	2020-09-05 (11)/ 2020-09-09 (15)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ BODY RASH	2020-09-29 (2)/ Ongoing	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932028; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-09-29 (2)/ 2020-10-06 (9)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932055; Age (years): 43; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Lip swelling/ TOP LIP SWELLING	2020-10-02 (2)/ 2020-10-03 (3)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3932117; Age (years): 35; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 11:30 (1)/ 2020-10-20 (6)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-10-16 08:00 (1)/ 2020-10-20 (6)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pruritus/ ITCHY AT INJECTION SITE	2020-10-16 08:00 (1)/ 2020-10-20 (6)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932130; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ RASH 1/2 INCH FROM INJECTION SITE	2020-09-24 (11)/ 2020-10-08 (25)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932158; Age (years): 56; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-21 (3)/ 2020-10-22 (4)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932160; Age (years): 64; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-21 (1)/ 2020-09-23 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932187; Age (years): 33; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ GENERALIZED ACHES	2020-09-29 (1)/ 2020-10-02 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932246; Age (years): 37; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-10 (1)/ Ongoing	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932250; Age (years): 75; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ RASH AT INJECTION SITE	2020-10-20 (7)/ 2020-10-24 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932276; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-17 12:00 (2)/ 2020-10-27 09:00 (11)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952019; Age (years): 65; Sex: M; Race: WHITE							
Investigations/ Blood pressure diastolic increased/ ELEVATED GRADE 3 DIASTOLIC BLOOD PRESSURE	2020-10-02 16:16 (1)/ 2020-10-02 16:30 (1)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952020; Age (years): 46; Sex: M; Race: WHITE							
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BLOOD PRESSURE	2020-09-01 14:11 (1)/ 2020-09-01 14:19 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952055; Age (years): 58; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ GRADE 3 BLOOD PRESSURE INCREASE	2020-09-08 16:08 (1)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3952100; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA	2020-09-24 (8)/ 2020-09-28 (12)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site warmth/ INJECTION SITE WARMTH	2020-09-24 (8)/ 2020-09-28 (12)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952106; Age (years): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Axillary pain/ LEFT UNDERARM PAIN	2020-09-23 (7)/ 2020-09-26 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3952106; Age (years): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE	2020-09-24 (8)/ 2020-09-26 (10)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-22 (2)/ 2020-11-09 (20)	Yes/ No/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3952118; Age (years): 33; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-20 03:15 (1)/ 2020-10-29 (11)	Yes/ No/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3952166; Age (years): 34; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ INCREASED FREQUENCY OF HEADACHES	2020-10-05 (8)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3952220; Age (years): 27; Sex: M; Race: ASIAN							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-10-09 16:07 (1)/ 2020-10-09 23:30 (1)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952221; Age (years): 38; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site haemorrhage/ INJECTION SITE ECCHYMOSIS	2020-10-12 11:31 (1)/ Ongoing	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962021; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-08-24 (1)/ 2020-09-02 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS - LEFT ELBOW	2020-08-25 (2)/ 2020-09-02 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS - SHOULDERS	2020-08-25 (2)/ 2020-09-02 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962021; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-08-25 (2)/ 2020-09-02 (10)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3962057; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-04 (3)/ 2020-09-16 (15)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	
Subject ID: US3962093; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ PRURITIS AT INJECTION SITE	2020-10-07 (1)/ 2020-10-13 (7)	Yes/ No/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962095; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-10-15 (4)/ 2020-10-20 (9)	Yes/ No/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3972036; Age (years): 38; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ ACNE OF THE LOWER BACK	2020-08-29 08:00 (3)/ 2020-09-02 (8)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-09-24 13:55 (2)/ 2020-09-24 21:00 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3972036; Age (years): 38; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-09-24 13:55 (2)/ 2020-09-24 21:00 (2)	Yes/ No/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3972046; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ LEFT SHOULDER REDNESS (MACULOPAPULAR/NON-URTIC ARIAL) OF SITE INJECTION	2020-09-04 (9)/ 2020-09-08 (13)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3972100; Age (years): 54; Sex: M; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ MILD THROAT ITCH	2020-09-03 11:15 (1)/ 2020-09-03 12:15 (1)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3972103; Age (years): 54; Sex: F; Race: MULTIPLE: (b) (6)							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-04 08:00 (1)/ 2020-09-06 08:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3972148; Age (years): 30; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-14 16:45 (1)/ 2020-09-17 07:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-14 16:45 (1)/ 2020-09-17 07:00 (3)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM PAIN	2020-09-15 14:30 (2)/ 2020-09-17 07:00 (3)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3972158; Age (years): 48; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-14 12:15 (2)/ 2020-10-15 09:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODYACHES	2020-10-14 12:15 (2)/ 2020-10-15 09:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ LOW GRADE FEVER 99.7	2020-10-14 12:15 (2)/ 2020-10-15 09:00 (2)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3972223; Age (years): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pyrexia/ FEVER OF 100.2 DEGREES FAHRENHEIT	2020-10-03 (3)/ 2020-10-04 (4)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3972224; Age (years): 27; Sex: M; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Urticaria/ HIVES ON ARM AND BACK	2020-10-14 (3)/ 2020-10-19 (8)	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3982020; Age (years): 60; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Asthma/ WORSENING OF ASTHMA	2020-08-27 23:30 (2)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982042; Age (years): 57; Sex: F; Race: WHITE							
Investigations/ Body temperature increased/ ELEVATED BODY TEMPERATURE UP TO 98.5 DEGREES FAHRENHEIT	2020-09-09 (13)/ 2020-09-23 (27)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Body temperature increased/ ELEVATED BODY TEMPERATURE UP TO 98.5 DEGREES FAHRENHEIT	2020-10-02 (2)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3982147; Age (years): 52; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-11 (2)/ 2020-10-14 (35)	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982158; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Idiopathic intracranial hypertension/ WORSENING PSEUDOTUMOR CEREBRI	2020-09-14 (4)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3982213; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site erythema/ LEFT DELTOID INJECTION SITE REDNESS	2020-09-21 15:00 (1)/ 2020-10-06 (16)	Yes/ No/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ LEFT DELTOID INJECTION SITE SWELLING	2020-09-21 15:00 (1)/ 2020-10-06 (16)	Yes/ No/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982213; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Respiratory tract infection viral/ VIRAL RESPIRATORY SYNDROME (MUSCLE ACHES, COUGH, FATIGUE, CHILLS, NAUSEA, VOMITING, SORE THROAT)	2020-09-24 (4)/ 2020-10-13 (23)	Yes/ No/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3992014; Age (years): 21; Sex: F; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash/ RASH ARMPITS	2020-10-19 19:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ ITCHY HIVES ON ARMS	2020-10-19 19:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992016; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-02 (11)/ 2020-10-09 (18)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3992070; Age (years): 23; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site pruritus/ INTERMITTENT INJECTION SITE ITCHING	2020-10-18 (12)/ Ongoing	Yes/ No/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.6
Unsolicited Treatment-Related TEAE
Safety Set

TEAE = Treatment-Emergent Adverse Event; MAAE = Medically-Attended Adverse Event; AR = Adverse Reaction; SAE = Serious Adverse Event; IP = Investigational Product; SP = Study Procedure.
Relative day is defined as days from the most recent injection date.
MedDRA version 23.0.
[1] Sev. = Severity, 1 = Grade 1/Mild, 2 = Grade 2/Moderate, 3 = Grade 3/Severe, 4 = Grade 4.
[2] 1 = Death, 2 = Life threatening, 3 = Requires inpatient or prolongation of existing Hospitalization (Hospital Admission Date/ Hospital Discharge Date), 4 = Persistent or significant disability or incapacity, 5 = Congenital anomaly or birth defect, 6 = Other medically important event.
[3] R = Related, NR = Not Related, NA = Not Applicable.

Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002046; Age (years): 60; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Hip fracture/ LEFT BROKEN HIP	2020-08-12 (15)/ 2020-08-14 (17)	Yes/ Yes/ No	3	Yes/3 (2020-08-12/)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3012195; Age (years): 52; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-08 (22)/ 2020-10-11 (25)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022065; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-24 (53)/ 2020-11-07 (67)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022065; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-24 (53)/ 2020-11-09 (69)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-24 (53)/ 2020-11-09 (69)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-25 (54)/ 2020-11-09 (69)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022083; Age (years): 66; Sex: F; Race: WHITE							
Surgical and medical procedures/ Carpal tunnel decompression/ CARPAL TUNNEL SURGERY LEFT HAND	2020-09-23 (14)/ 2020-09-23 (14)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022119; Age (years): 46; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTROINTESTINAL HEMORRHAGE	2020-10-16 (23)/ 2020-10-16 (23)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032110; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-18 (72)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042309; Age (years): 39; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ SEVERE BODY ACHES	2020-09-16 (26)/ 2020-09-29 (39)	Yes/ No/ No	3	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ SEVERE MUSCLE ACHES	2020-09-16 (26)/ 2020-09-29 (39)	Yes/ No/ No	3	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3052295; Age (years): 38; Sex: F; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE	2020-09-24 14:08 (2)/ 2020-09-25 10:18 (2)	Yes/ Yes/ No	3	Yes/3 (2020-09-24/ 2020-09-26)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3052307; Age (years): 54; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-28 18:13 (1)/ 2020-09-02 21:48 (6)	Yes/ No/ No	3	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082038; Age (years): 47; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ BACK SPRAIN	2020-08-22 (6)/ 2020-09-09 (24)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082052; Age (years): 69; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant melanoma/ MELANOMA ON RIGHT CALF	2020-08-21 (4)/ 2020-08-28 (11)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3082170; Age (years): 70; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION (POST-DOSE)	2020-09-01 13:55 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112162; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-08-27 (18)/ 2020-08-29 (20)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112173; Age (years): 77; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ PAIN SECONDARY TO SPINAL FUSION	2020-08-25 (16)/ 2020-09-21 (43)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112223; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP-PHARYNGITIS	2020-09-01 (20)/ 2020-09-14 (33)	Yes/ Yes/ No	3	Yes/3 (2020-09-02/ 2020-09-03)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112260; Age (years): 57; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle rupture/ RIGHT UPPER ARM MUSCLE TEAR	2020-09-19 (10)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112289; Age (years): 31; Sex: F; Race: ASIAN							
Injury, poisoning and procedural complications/ Procedural haemorrhage/ BLEEDING FROM SURGICAL SITE	2020-10-05 (21)/ 2020-10-06 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112395; Age (years): 32; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-05 (13)/ 2020-10-07 (15)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3142252; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-07 (47)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152020; Age (years): 43; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-07-28 18:44 (1)/ 2020-07-29 15:00 (1)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152194; Age (years): 54; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ BILATERAL PULMONARY EMBOLISM WITH PULMONARY INFARCTS	2020-09-21 (11)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152357; Age (years): 51; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-21 17:50 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152386; Age (years): 49; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-09-26 00:00 (1)/ 2020-09-29 00:00 (4)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152402; Age (years): 40; Sex: F; Race: MULTIPLE:				(b) (6)			
Musculoskeletal and connective tissue disorders/ Undifferentiated connective tissue disease/ UNDIFFERENTIATED CONNECTIVE TISSUE DISEASE	2020-11-05 (29)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162006; Age (years): 75; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-11-10 (79)/ 2020-11-11 (80)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162064; Age (years): 51; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foreign body/ WOODEN FOREIGN BODY LEFT SOLE	2020-10-27 (57)/ 2020-11-04 (65)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172038; Age (years): 34; Sex: F; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ RIGHT KIDNEY ACUTE NEPHROLITHIASIS	2020-08-29 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Renal colic/ ACUTE RENAL COLIC	2020-08-29 (19)/ 2020-08-30 (20)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Pyelonephritis/ UNRESOLVED RIGHT KIDNEY PYELONEPHRITIS	2020-09-22 (43)/ 2020-09-26 (47)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172069; Age (years): 68; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-09-04 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172185; Age (years): 61; Sex: M; Race: WHITE							
Cardiac disorders/ Acute left ventricular failure/ ACUTE EXACERBATION OF SYSTOLIC HEART FAILURE	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILATION WITH RAPID VENTRICULAR RATE	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172185; Age (years): 61; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172205; Age (years): 55; Sex: F; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-10-14 (29)/ 2020-10-25 (40)	Yes/ No/ No	3	Yes/3 (2020-10-14/ 2020-10-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172250; Age (years): 59; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ ACUTE EXACERBATION OF CONGESTION HEART FAILURE	2020-09-12 (24)/ 2020-09-16 (28)	Yes/ Yes/ No	3	Yes/3 (2020-09-12/ 2020-09-16)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172322; Age (years): 51; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ WORSENING OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE	2020-10-10 (17)/ 2020-11-12 (50)	Yes/ Yes/ No	3	Yes/3 (2020-10-10/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3182227; Age (years): 69; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ LEFT ROTATOR CUFF TEAR	2020-09-25 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3222015; Age (years): 85; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-06 15:33 (1)/ 2020-08-07 16:03 (2)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222031; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION - EXACERBATION	2020-08-07 12:51 (1)/ Ongoing	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3222059; Age (years): 84; Sex: F; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ NEW ONSET-ATRIAL FIBRILLATION	2020-09-03 (27)/ 2020-09-05 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-05)/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222242; Age (years): 57; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Thyroid cancer/ THYROID CANCER	2020-10-01 (16)/ 2020-10-20 (35)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222430; Age (years): 60; Sex: M; Race: WHITE							
Surgical and medical procedures/ Jaw operation/ JAW SURGERY	2020-11-05 (36)/ 2020-11-06 (37)	Yes/ Yes/ No	3	Yes/3 (2020-11-05/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3222611; Age (years): 55; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Gait disturbance/ GAIT DYSFUNCTION AND ADL'S AND SELF-CARE DEFICITS	2020-10-29 (15)/ 2020-11-10 (27)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: NO BILATERAL FEET CONTROL, RIGHT SIDE OF BODY PARALYSIS.
Nervous system disorders/ Aphasia/ MILD EXPRESSIVE AND RECEPTIVE AND RECEPTIVE APHASIA.	2020-10-29 (15)/ 2020-11-10 (27)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: RESIDUAL EFFECTS FROM CVA

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222611; Age (years): 55; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-29 (15)/ 2020-11-10 (27)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: ALTHOUGH NOW TREATED WITH MEDICATION WILL CONTINUE WITH DIAGNOSIS
Metabolism and nutrition disorders/ Dyslipidaemia/ DYSLIPIDEMIA	2020-10-29 (15)/ 2020-11-15 (32)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: THIS HAS BEEN TREATED WITH MEDICATION HOWEVER WILL NEVER RESOLVE WITHOUT MEDICATION.

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242051; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ankle fracture/ TRIMALLEOLAR ANKLE FRACTURE, RIGHT	2020-11-01 (52)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-02/ 2020-11-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3242065; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS, LOWER LEFT LEG	2020-09-19 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Phlebitis/ PHIEBITIS	2020-09-19 (9)/ 2020-10-03 (23)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242132; Age (years): 65; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL CARCINOMA, LOWER LEG, LEFT	2020-09-01 (15)/ 2020-10-12 (56)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3242246; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-09-11 (15)/ 2020-10-02 (36)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242258; Age (years): 76; Sex: F; Race: WHITE							
Infections and infestations/ Pneumonia/ COMMUNITY ACQUIRED PNEUMONIA	2020-09-15 (16)/ 2020-10-22 (53)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242258; Age (years): 76; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA, SEVERE PERSISTENT	2020-10-05 (36)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242264; Age (years): 49; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Facial bones fracture/ BROKEN NOSE	2020-11-20 (54)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Skin laceration/ HEAD LACERATION	2020-11-20 (54)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-20/ 2020-11-22)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242279; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ DENTAL ABSCESS	2020-09-14 (13)/ 2020-09-20 (19)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3242397; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-03 (5)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-10-31 (5)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252602; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-11-06 (8)/ 2020-11-06 (8)	Yes/ Yes/ No	3	Yes/3 (2020-11-06/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3272085; Age (years): 58; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ WORSENING INTERMITTENT CHEST WALL PAIN NON CARDIAC	2020-10-07 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-09/ 2020-10-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272195; Age (years): 44; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Hypoxia/ HYPOXIA	2020-11-07 (52)/ 2020-11-12 (57)	Yes/ Yes/ No	3	Yes/3 (2020-11-07/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272206; Age (years): 65; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-30 (14)/ 2020-10-07 (21)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272342; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-01 (8)/ 2020-10-10 (17)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282025; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES, MULTIPLE SITES	2020-08-16 (7)/ 2020-08-22 (13)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292320; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Cartilage injury/ LEFT HIP LABRUM TEAR	2020-08-27 (3)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-30/ 2020-09-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3292407; Age (years): 48; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-10-27 (8)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3302383; Age (years): 54; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE RESPIRATORY FAILURE	2020-09-26 (32)/ 2020-09-28 (34)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-28)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312075; Age (years): 20; Sex: F; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-09-29 (15)/ 2020-09-29 (15)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312113; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-19 (34)/ 2020-10-19 (34)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-19 (34)/ 2020-10-19 (34)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-19 (34)/ 2020-10-25 (40)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312130; Age (years): 50; Sex: M; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-16 (29)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312171; Age (years): 50; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-17 (32)/ 2020-10-20 (35)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312198; Age (years): 83; Sex: M; Race: WHITE							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-09-17 10:47 (1)/ 2020-09-17 21:00 (1)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312201; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-08-24 (5)/ 2020-10-09 (51)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312201; Age (years): 65; Sex: M; Race: WHITE							
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BLOOD PRESSURE	2020-10-28 (70)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-28 (70)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312212; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Osteomyelitis/ LEFT GREAT TOE OSTEOMYELITIS	2020-09-04 (15)/ 2020-10-16 (57)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-09)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: RECOVERED WITH SEQUALAE LEFT GREAT TOE AMPUTATION

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312258; Age (years): 52; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-20 (29)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BLOOD PRESSURE	2020-10-20 (29)/ 2020-10-20 (29)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312434; Age (years): 69; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-09-29 11:37 (28)/ 2020-10-27 11:17 (56)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312548; Age (years): 65; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-10-07 (30)/ 2020-11-03 (57)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312605; Age (years): 24; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-19 (12)/ 2020-11-02 (26)	Yes/ Yes/ No	3	Yes/3 (2020-10-27/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312626; Age (years): 47; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-09-11 (1)/ 2020-09-15 (5)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312627; Age (years): 49; Sex: M; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-09-11 12:47 (1)/ 2020-09-29 (19)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312629; Age (years): 53; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2020-11-06 (25)/ 2020-11-10 (29)	Yes/ Yes/ No	3	Yes/3 (2020-11-06/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322003; Age (years): 51; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-21 (39)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3322006; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-08 (53)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3322013; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Syncope/ CONVULSIVE SYNCOPE	2020-09-14 (29)/ 2020-09-14 (29)	Yes/ No/ No	3	Yes/6	NR/ R	DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3322036; Age (years): 28; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 (6)/ 2020-10-06 (16)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322377; Age (years): 27; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ ABDOMINAL PAIN, LEFT UPPER QUADRANT	2020-10-12 (25)/ 2020-10-12 (25)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3332001; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-30 (34)/ 2020-10-02 (36)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3332017; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-08-23 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332067; Age (years): 77; Sex: M; Race: WHITE							
Investigations/ Blood pressure systolic increased/ GRADE 3 ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-21 (30)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3342199; Age (years): 59; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Colitis/ ACUTE FOCAL COLITIS	2020-09-13 (10)/ 2020-09-25 (22)	Yes/ Yes/ No	3	Yes/3 (2020-09-13/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342200; Age (years): 44; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Intraductal proliferative breast lesion/ DUCTAL CARCINOMA IN SITU RIGHT BREAST	2020-11-20 (52)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342259; Age (years): 41; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression suicidal/ DEPRESSION WITH SUICIDAL IDEATION	2020-10-14 (31)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3352041; Age (years): 61; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Systolic hypertension/ ELEVATED SYSTOLIC HYPERTENSION	2020-08-11 11:35 (1)/ 2020-09-08 10:08 (28)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352095; Age (years): 63; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ GRADE 3 INCREASED SYSTOLIC BLOOD PRESSURE	2020-08-13 18:01 (1)/ 2020-09-08 14:53 (26)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352145; Age (years): 59; Sex: M; Race: WHITE							
Vascular disorders/ Systolic hypertension/ HYPERTENSION (SYSTOLIC)	2020-08-20 11:50 (1)/ 2020-10-15 09:00 (56)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352254; Age (years): 63; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-22 09:28 (28)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	
Subject ID: US3352424; Age (years): 53; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-05 (12)/ 2020-10-18 (25)	Yes/ Yes/ No	3	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352479; Age (years): 64; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-29 18:56 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3352500; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-11 (9)/ 2020-11-15 (13)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352574; Age (years): 62; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-18 10:26 (34)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362053; Age (years): 51; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ WORSENING OF MIGRAINE/HEADACHE	2020-09-05 00:00 (1)/ 2020-09-19 00:00 (15)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372005; Age (years): 94; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Hip fracture/ FRACTURED LEFT HIP	2020-08-25 (22)/ 2020-08-26 (23)	Yes/ No/ No	3	Yes/3 (2020-08-25/ 2020-08-31)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3372184; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-09-02 (15)/ 2020-09-02 (15)	Yes/ No/ No	3	Yes/3 (2020-09-02/ 2020-09-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372427; Age (years): 61; Sex: F; Race: ASIAN							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Breast cancer/ MALIGNANT RIGHT BREAST TUMOR	2020-09-18 (3)/ 2020-10-20 (35)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3382155; Age (years): 41; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 (8)/ 2020-10-09 (12)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3392318; Age (years): 44; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foreign body/ FORIEGN BODY, RIGHT INDEX FINGER	2020-10-06 (19)/ 2020-10-06 (19)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402194; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-05 (65)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-16/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402299; Age (years): 50; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ SEVERE HEADACHE	2020-08-11 (4)/ 2020-08-16 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Post procedural haemorrhage/ POST OPERATIVE BLEEDING	2020-08-26 (19)/ 2020-09-01 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-26/ 2020-09-01)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3402382; Age (years): 66; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-08-28 (13)/ 2020-09-01 (17)	Yes/ Yes/ No	3	Yes/3 (2020-08-28/ 2020-09-01)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402425; Age (years): 36; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2020-11-17 (54)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-17/)	NA/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402448; Age (years): 66; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Emphysema/ WORSENING OF EMPHYSEMA	2020-11-09 (20)/ 2020-11-11 (22)	Yes/ Yes/ No	3	Yes/3 (2020-11-09/ 2020-11-11)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT WAS SENT HOME ON 2 LITERS OF CONTINUOUS OXYGEN
Subject ID: US3412328; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN (ETIOLOGY - UNDETERMINED)	2020-09-05 (11)/ 2020-10-01 (37)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422006; Age (years): 39; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-26 (15)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3422011; Age (years): 39; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Femoral hernia/ FEMORAL HERNIA	2020-08-20 (8)/ 2020-08-28 (16)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422281; Age (years): 65; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS	2020-10-27 (14)/ 2020-10-28 (15)	Yes/ Yes/ No	3	Yes/3 (2020-10-27/ 2020-10-28)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422286; Age (years): 59; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-07 (22)/ 2020-10-14 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432023; Age (years): 83; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Polymyalgia rheumatica/ POSSIBLE POLYMYALGIA RHEUMATICA	2020-08-20 (16)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-21)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3432135; Age (years): 32; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-30 (21)/ 2020-10-08 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432183; Age (years): 26; Sex: F; Race: WHITE							
Nervous system disorders/ Seizure/ SEIZURE	2020-10-09 (12)/ 2020-10-09 (12)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432202; Age (years): 77; Sex: M; Race: WHITE							
Vascular disorders/ Hypertensive urgency/ HYPERTENSIVE URGENCY	2020-09-25 (10)/ 2020-09-30 (15)	Yes/ Yes/ No	3	Yes/3 (2020-09-25/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432202; Age (years): 77; Sex: M; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-02 (17)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432208; Age (years): 54; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ SPINAL STENOSIS	2020-09-07 (19)/ 2020-10-05 (47)	Yes/ Yes/ No	3	Yes/3 (2020-10-02/ 2020-10-05)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432260; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
Surgical and medical procedures/ Spinal fusion surgery/ CERVICAL FUSION C5-C6	2020-11-04 (45)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-04/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432402; Age (years): 62; Sex: M; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE 182 MM/HG	2020-09-30 11:14 (28)/ 2020-09-30 12:15 (28)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432415; Age (years): 74; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-02 (1)/ 2020-10-03 (2)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432585; Age (years): 30; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Costochondritis/ COSTOCHONDRITIS	2020-10-25 (24)/ 2020-11-03 (33)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3442004; Age (years): 69; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-13 13:33 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442145; Age (years): 55; Sex: M; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-10-09 14:44 (26)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Investigations/ Blood pressure increased/ WORSENING ELEVATED BLOOD PRESSURE	2020-10-09 14:44 (26)/ 2020-10-09 15:49 (26)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462299; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (48)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3462305; Age (years): 50; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRYALGIA IN BOTH LEGS (POST-DOSE)	2020-08-24 16:33 (1)/ 2020-09-01 13:00 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482098; Age (years): 70; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE LEFT SIDE	2020-10-01 (15)/ 2020-10-03 (17)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482145; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Gout/ GOUT EXACERBATION IN RIGHT KNEE	2020-09-26 (32)/ 2020-09-30 (36)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Renal and urinary disorders/ Chronic kidney disease/ ACUTE EXACERBATION OF CHRONIC KIDNEY DISEASE STAGE III	2020-09-26 (32)/ 2020-09-30 (36)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482145; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Anaemia/ EXACERBATION OF ANEMIA	2020-10-22 (58)/ 2020-10-26 (62)	Yes/ Yes/ No	3	Yes/3 (2020-10-22/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3482208; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Abdominal discomfort/ GI DISTRESS	2020-09-24 (23)/ 2020-09-29 (28)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	2020-09-25 (24)/ 2020-09-25 (24)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482267; Age (years): 78; Sex: F; Race: WHITE							
Nervous system disorders/ Presyncope/ VASOVAGAL SYNDROME	2020-10-08 12:56 (1)/ 2020-10-08 14:30 (1)	Yes/ Yes/ No	3	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492020; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-11 (17)/ 2020-10-16 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-11 (17)/ 2020-10-16 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492064; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Cerebrovascular accident/ CEREBROVASCULAR ACCIDENT	2020-10-31 (30)/ 2020-11-11 (41)	Yes/ Yes/ No	3	Yes/3 (2020-10-31/ 2020-11-11)/4	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: RIGHT LOWER EXTREMITY WEAKNESS

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492085; Age (years): 29; Sex: F; Race: NOT REPORTED							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-09-24 (17)/ 2020-10-25 (48)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492130; Age (years): 70; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-27 (19)/ 2020-10-30 (22)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492152; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ PULLED GROIN MUSCLE	2020-09-26 (13)/ 2020-10-05 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492178; Age (years): 68; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Foot deformity/ PAIN FROM BUNION TO RIGHT FOOT	2020-09-17 12:00 (1)/ 2020-09-18 22:00 (2)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492190; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Tendonitis/ SHOULDER TENDONITIS	2020-10-13 (27)/ 2020-10-30 (44)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492199; Age (years): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Insomnia/ INSOMNIA	2020-11-03 (19)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3492213; Age (years): 27; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-16 (28)/ 2020-10-25 (37)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502045; Age (years): 55; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ MIGRAINE EXACERBATION	2020-09-16 (20)/ 2020-09-23 (27)	Yes/ Yes/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502216; Age (years): 39; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Immune system disorders/ Anaphylactic reaction/ ANAPHYLAXIS	2020-11-02 (11)/ 2020-11-02 (11)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512049; Age (years): 64; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL INJECTION SITE AXILLARY LYMPHADENOPATHY	2020-09-10 07:00 (1)/ 2020-09-19 12:00 (10)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512055; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-11 (32)/ 2020-10-11 (32)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512055; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-15 (36)/ Ongoing	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 (36)/ Ongoing	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-15 (36)/ Ongoing	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 (36)/ 2020-10-15 (36)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512064; Age (years): 65; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ LEFT POSTERIOR TENDONITIS	2020-10-06 (27)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512082; Age (years): 68; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ EXERCISE WORSENED BACK MUSCLE SPASMS	2020-10-19 (39)/ 2020-10-29 (49)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512092; Age (years): 64; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-12 07:00 (1)/ 2020-09-22 07:00 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512115; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 (7)/ 2020-08-28 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-30 10:00 (2)/ Ongoing	Yes/ No/ Yes	3	No	R/ R	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-31 (3)/ 2020-09-20 (23)	Yes/ No/ Yes	3	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512206; Age (years): 75; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA ON SCALP	2020-09-16 (14)/ 2020-09-29 (27)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3522446; Age (years): 62; Sex: M; Race: UNKNOWN							
General disorders and administration site conditions/ Fatigue/ SEVERE FATIGUE	2020-10-07 (9)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522536; Age (years): 65; Sex: F; Race: OTHER: (b) (6)							
Injury, poisoning and procedural complications/ Muscle strain/ BACK STRAIN	2020-10-19 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522583; Age (years): 33; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522583; Age (years): 33; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ CHEST CONGESTION	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522583; Age (years): 33; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3532158; Age (years): 75; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Penile cancer/ CANCEROUS TUMOR-PENIS	2020-11-16 (55)/ Ongoing	Yes/ Yes/ No	3	Yes/2	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3532170; Age (years): 66; Sex: F; Race: WHITE							
Cardiac disorders/ Ventricular fibrillation/ VENTRICULAR FIBRILLATION-INTERMEDIATE	2020-09-08 (13)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532170; Age (years): 66; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-12 (17)/ 2020-10-09 (44)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532238; Age (years): 78; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE	2020-10-29 (29)/ 2020-10-29 (29)	Yes/ No/ No	3	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532272; Age (years): 33; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-10-11 (5)/ 2020-10-12 (6)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542019; Age (years): 70; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	2020-09-25 (11)/ 2020-10-01 (17)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542053; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN, LOWER	2020-09-25 (5)/ 2020-10-02 (12)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542168; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Anxiety/ ANXIETY EXACERBATION	2020-09-19 (16)/ 2020-09-23 (20)	Yes/ Yes/ No	3	Yes/3 (2020-09-19/ 2020-09-23)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Depression/ DEPRESSION EXACERBATION	2020-09-19 (16)/ 2020-09-23 (20)	Yes/ Yes/ No	3	Yes/3 (2020-09-19/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552140; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Eye disorders/ Retinal detachment/ RETINAL DETACHMENT OF LEFT EYE	2020-09-08 (18)/ 2020-09-12 (22)	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552140; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Eye disorders/ Retinal tear/ HORSESHOE TEAR OF RIGHT EYE	2020-10-01 (41)/ 2020-10-06 (46)	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3552273; Age (years): 52; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-09-01 14:07 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3552398; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Joint injury/ RIGHT KNEE INJURY	2020-09-17 (8)/ 2020-09-28 (19)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552424; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Oedema peripheral/ LEFT LEG EDEMA	2020-11-13 (37)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552452; Age (years): 53; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-14 (28)/ 2020-10-15 (29)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572134; Age (years): 48; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-11-09 (42)/ 2020-11-13 (46)	Yes/ Yes/ No	3	Yes/3 (2020-11-09/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3572167; Age (years): 43; Sex: M; Race: WHITE							
Vascular disorders/ Accelerated hypertension/ ACELERATED HYPERTENSION	2020-10-27 (27)/ 2020-10-30 (30)	Yes/ No/ No	3	Yes/3 (2020-10-27/ 2020-10-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3582001; Age (years): 63; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-09-11 (25)/ 2020-09-13 (27)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582026; Age (years): 73; Sex: F; Race: WHITE							
Vascular disorders/ Systolic hypertension/ SYSTOLIC HYPERTENSION	2020-10-13 (28)/ 2020-10-19 (34)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582033; Age (years): 76; Sex: M; Race: MULTIPLE: (b) (6)							
Vascular disorders/ Hypertension/ HIGH BLOOD PRESSURE	2020-08-24 13:40 (1)/ 2020-09-04 07:31 (11)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582109; Age (years): 70; Sex: F; Race: WHITE							
Vascular disorders/ Systolic hypertension/ SYSTOLIC HYPERTENSION	2020-09-04 17:35 (1)/ 2020-10-08 (35)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-09-14 (11)/ 2020-09-14 (11)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582128; Age (years): 58; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-09-10 09:35 (1)/ 2020-10-05 16:05 (26)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582180; Age (years): 37; Sex: M; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN EXACERBATION	2020-11-16 (15)/	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	
Subject ID: US3582190; Age (years): 60; Sex: M; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-19 16:30 (1)/ 2020-11-08 12:00 (20)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-16 15:11 (28)/	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602051; Age (years): 52; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ RIB PAIN (BILATERAL) PAIN SCALE: 8/10	2020-10-27 (14)/ 2020-10-31 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3622011; Age (years): 80; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Skin cancer/ BACK SKIN CANCER	2020-10-14 (37)/ 2020-10-14 (37)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622012; Age (years): 23; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-08-29 (19)/ 2020-09-04 (25)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632023; Age (years): 70; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-25 12:00 (28)/ 2020-09-25 14:46 (28)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632033; Age (years): 75; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-05 08:22 (31)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632048; Age (years): 53; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-01 13:30 (1)/ Ongoing	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632126; Age (years): 22; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Genital herpes/ GENITAL HERPES	2020-10-18 (6)/ 2020-11-09 (28)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 (8)/ 2020-10-21 (9)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652002; Age (years): 85; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION (ELEVATED BLOOD PRESSURE AT DAY 29)	2020-09-25 10:21 (30)/ 2020-09-25 12:01 (30)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652004; Age (years): 67; Sex: M; Race: OTHER: (b) (6)							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-09-01 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662033; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Appendicitis/ ACUTE APPENDICITIS	2020-09-08 (8)/ 2020-09-09 (9)	Yes/ Yes/ No	3	Yes/3 (2020-09-08/ 2020-09-10)/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662033; Age (years): 67; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-08 (8)/ 2020-09-10 (10)	Yes/ Yes/ No	3	Yes/3 (2020-09-08/ 2020-09-10)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3662124; Age (years): 37; Sex: M; Race: OTHER: (b) (6)							
Surgical and medical procedures/ Endodontic procedure/ PERFORATION OF ROOT CANAL SPACE DUE TO ENDODONTIC TREATMENT	2020-11-12 (24)/ 2020-11-12 (24)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662181; Age (years): 61; Sex: M; Race: MULTIPLE: (b) (6)							
Psychiatric disorders/ Psychotic disorder/ PSYCHOSIS, UNSPECIFIED	2020-10-26 (5)/ 2020-10-30 (9)	Yes/ Yes/ No	3	Yes/3 (2020-10-26/ 2020-10-30)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672187; Age (years): 72; Sex: M; Race: WHITE							
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BLOOD PRESSURE	2020-09-21 (34)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3672199; Age (years): 71; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Post procedural haematoma/ HEMATOMA R GROIN FOLLOWING ANGIOPLASTY	2020-10-06 (19)/ 2020-10-08 (21)	Yes/ Yes/ No	3	Yes/3 (2020-10-06/ 2020-10-08)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3682139; Age (years): 33; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-30 (14)/ 2020-10-01 (15)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682139; Age (years): 33; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Asthenia/ WEAKNESS	2020-09-30 (14)/ 2020-10-04 (18)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-30 (14)/ 2020-10-04 (18)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692002; Age (years): 55; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-02 (36)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692046; Age (years): 50; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF BACK PAIN	2020-09-17 (14)/ 2020-09-17 (14)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692049; Age (years): 61; Sex: F; Race: WHITE							
Vascular disorders/ Hypotension/ HYPOTENSION	2020-11-03 (35)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692052; Age (years): 72; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-30 (29)/ 2020-10-30 (29)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692065; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-09-27 (23)/ 2020-10-03 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692074; Age (years): 48; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-04 (29)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692088; Age (years): 56; Sex: M; Race: WHITE							
Vascular disorders/ Diastolic hypertension/ DIASTOLIC HYPERTENSION	2020-10-08 (29)/ 2020-10-16 (37)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692112; Age (years): 69; Sex: M; Race: WHITE							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-09-14 12:40 (1)/ 2020-10-12 13:01 (29)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692117; Age (years): 47; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-10-05 (20)/ 2020-10-11 (26)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692138; Age (years): 35; Sex: M; Race: UNKNOWN							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-18 13:16 (1)/ 2020-10-23 14:27 (36)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692146; Age (years): 37; Sex: M; Race: ASIAN							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-10-23 14:55 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692199; Age (years): 35; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-11-02 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Depression/ DEPRESSION	2020-11-02 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3702002; Age (years): 39; Sex: M; Race: MULTIPLE:				(b) (6)			
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-27 (3)/ 2020-09-22 (29)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3702042; Age (years): 80; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypotension/ HYPOTENSION	2020-09-22 12:36 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702044; Age (years): 47; Sex: F; Race: WHITE							
Immune system disorders/ Drug hypersensitivity/ MACROBID ALLERGIC REACTION	2020-11-09 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3702051; Age (years): 43; Sex: F; Race: UNKNOWN							
Injury, poisoning and procedural complications/ Procedural pain/ RGHT KNEE PAIN (POST ARTHROSCOPIC SURGERY ON 10/22/2020)	2020-10-22 (21)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Joint swelling/ RIGHT KNEE SWELLING	2020-10-22 (21)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722034; Age (years): 65; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer metastatic/ METASTATIC CASTRATE SENSITIVE PROSTRATE CANCER WITH METASTASES	2020-09-23 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3722066; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ POSITIVE COVID 19	2020-11-11 (76)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-16/)	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3722157; Age (years): 39; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-08 (5)/ 2020-09-08 (5)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722217; Age (years): 39; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES BILATERAL LEGS	2020-08-15 (4)/ 2020-08-22 (11)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722338; Age (years): 73; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Umbilical hernia/ UMBILICAL HERNIA	2020-10-13 (27)/ 2020-10-21 (35)	Yes/ Yes/ No	3	Yes/3 (2020-10-13/ 2020-10-21)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732090; Age (years): 78; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-18 15:06 (1)/ 2020-10-05 (49)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732304; Age (years): 55; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ BILATERAL PULMONARY EMBOLISM	2020-10-29 (23)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-29/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3732317; Age (years): 48; Sex: F; Race: ASIAN							
Nervous system disorders/ Presyncope/ VASOVAGAL EPISODE	2020-10-15 (1)/ 2020-10-15 (1)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732368; Age (years): 32; Sex: M; Race: ASIAN							
Vascular disorders/ Hypertension/ HYPTERTENSION	2020-09-22 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3742046; Age (years): 64; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Aortic aneurysm/ THORACIC ANEURYSM	2020-10-12 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742083; Age (years): 43; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-10-01 (10)/ 2020-10-02 (11)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742336; Age (years): 79; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HIGH BLOOD PRESSURE	2020-10-08 09:41 (27)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742342; Age (years): 18; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Major depression/ MAJOR DEPRESSIVE DISORDER WITHOUT PSYCHOTIC FEATURES	2020-09-16 (6)/ 2020-09-17 (7)	Yes/ Yes/ No	3	Yes/3 (2020-09-16/ 2020-09-17)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742384; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-11-01 (20)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-01/ 2020-11-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742395; Age (years): 61; Sex: M; Race: OTHER: (b) (6)							
Vascular disorders/ Deep vein thrombosis/ DEEP VEIN THROMBOSIS	2020-09-25 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752161; Age (years): 70; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Lumbar vertebral fracture/ CLOSED FRACTURE OF 2ND AND 3RD LUMBAR	2020-09-16 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT	2020-09-16 (1)/ 2020-09-16 (1)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-09-16 (1)/ 2020-09-16 (1)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752162; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ L5 S1 DISCECTOMY WITH RIGHT LATERAL HEMILAMINECTOMY DUE TO LOW BACK PAIN	2020-10-15 (30)/ 2020-10-15 (30)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3752180; Age (years): 57; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-25 (6)/ 2020-08-30 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772032; Age (years): 57; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tibia fracture/ FRACTURED TIBIA	2020-08-29 (20)/ 2020-09-03 (25)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772051; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Incarcerated hernia/ ACUTE INCARCERATED VENTRAL HERNIA	2020-09-04 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-05/ 2020-09-14)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-09-05 (25)/ 2020-09-14 (34)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3782016; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-09 (29)/ 2020-11-09 (60)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782050; Age (years): 30; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-18 (33)/ 2020-11-06 (52)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782073; Age (years): 56; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Angioedema/ ANGIODEMA	2020-08-28 (5)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3782082; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-31 (40)/ 2020-11-23 (63)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782152; Age (years): 55; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-09-04 13:52 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3792079; Age (years): 48; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-29 13:37 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802046; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-13 (52)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-21/ 2020-11-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3812007; Age (years): 82; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-04 08:50 (32)/ 2020-11-03 (93)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812272; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-13 (51)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822019; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Asthma/ WORSENING OF ASTHMA	2020-08-10 (6)/ 2020-08-10 (6)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822019; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Asthma/ WORSENING OF ASTHMA	2020-08-20 (16)/ 2020-08-20 (16)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822118; Age (years): 72; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH, GENERALIZED	2020-10-02 (23)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3822119; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-03 08:00 (21)/ 2020-09-06 (25)	Yes/ Yes/ No	3	Yes/3 (2020-09-04/ 2020-09-06)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822158; Age (years): 26; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (2)/ 2020-09-26 (10)	Yes/ No/ Yes	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822288; Age (years): 42; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Dysmenorrhoea/ EXTREME MENSTRUAL CRAMPING	2020-09-16 (21)/ 2020-09-17 (22)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3832014; Age (years): 56; Sex: F; Race: WHITE							
Vascular disorders/ Hypertensive emergency/ HYPERTENSIVE EMERGENCY	2020-08-31 (4)/ 2020-09-02 (6)	Yes/ Yes/ No	3	Yes/3 (2020-08-31/ 2020-09-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832074; Age (years): 82; Sex: F; Race: WHITE							
Cardiac disorders/ Acute myocardial infarction/ ST ELEVATION MYOCARDIAL INFARCTION (UNSPECIFIED ARTERY)	2020-09-16 (44)/ 2020-09-18 (46)	Yes/ Yes/ No	3	Yes/3 (2020-09-16/ 2020-09-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832211; Age (years): 76; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ COPD EXACERBATION	2020-10-08 (24)/ 2020-10-16 (32)	Yes/ Yes/ No	3	Yes/3 (2020-10-08/ 2020-10-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852014; Age (years): 60; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-09-12 (20)/ 2020-09-19 (27)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862053; Age (years): 74; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-23 12:45 (32)/ 2020-10-31 (41)	Yes/ Yes/ No	3	Yes/3 (2020-10-23/ 2020-10-31)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862098; Age (years): 45; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ NEW HTN DIAGNOSIS	2020-09-29 (30)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872033; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ WORSENING OF BRONCHITIS	2020-08-29 (26)/ 2020-09-05 (33)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872067; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ LOCALIZE MUSCULOSKELETAL DISCOMFORT CHEST	2020-08-15 (10)/ 2020-08-17 (12)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872138; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-27 (17)/ 2020-09-08 (29)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-08-31 (21)/ 2020-08-31 (21)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872138; Age (years): 73; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Retching/ DRY HEAVES	2020-08-31 (21)/ 2020-08-31 (21)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3872191; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ ACUTE BRONCHITIS	2020-09-10 (28)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3872253; Age (years): 30; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Gingivitis/ WORESNING OF GINGIVITIS	2020-09-03 (14)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3872334; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF LEFT SHOULDER ULNOHUMERAL ARTHRITIS	2020-09-22 (27)/ 2020-09-23 (28)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872384; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Gingivitis/ GUM INFECTION	2020-10-05 (36)/ 2020-10-14 (45)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3902064; Age (years): 50; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-18 (9)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912006; Age (years): 71; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION- GRADE 3	2020-08-26 12:51 (1)/ 2020-08-26 14:05 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912007; Age (years): 66; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ WORSENING OF CONGESTIVE HEART FAILURE	2020-09-24 (30)/ 2020-10-23 (59)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912007; Age (years): 66; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-24 (30)/ 2020-10-23 (59)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912026; Age (years): 72; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION (GRADE 3)	2020-09-25 11:42 (1)/ 2020-09-25 11:54 (1)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912028; Age (years): 75; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS, LEFT SHOULDER	2020-09-28 (32)/ 2020-09-28 (32)	Yes/ No/ No	3	Yes/3 (2020-09-28/ 2020-09-29)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912046; Age (years): 59; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION (WORSENING OF)	2020-09-08 (9)/ 2020-09-24 (25)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912046; Age (years): 59; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION (WORSENING OF)	2020-10-26 (29)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912051; Age (years): 68; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE GRADE 3	2020-08-31 15:25 (1)/ 2020-08-31 15:35 (1)	Yes/ No/ No	3	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE GRADE 3	2020-09-15 (16)/ 2020-09-15 (16)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912058; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION (WORSENING OF)	2020-09-01 12:55 (1)/ 2020-09-01 13:11 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912058; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-29 13:12 (1)/ 2020-10-27 09:59 (28)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-09-29 13:12 (1)/ 2020-10-27 10:04 (28)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912067; Age (years): 63; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-01 16:13 (1)/ 2020-10-27 (57)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912099; Age (years): 73; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-03 17:30 (1)/ 2020-09-03 17:39 (1)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912103; Age (years): 68; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-02 (29)/ 2020-10-09 (36)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912111; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-04 16:19 (1)/ 2020-09-04 16:30 (1)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION-GRADE 3	2020-10-01 13:42 (1)/ 2020-10-01 13:52 (1)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912118; Age (years): 69; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-08 11:37 (1)/ 2020-09-08 14:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912118; Age (years): 69; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-06 12:20 (1)/ 2020-10-06 14:44 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912124; Age (years): 55; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Vascular disorders/ Hypertension/ HYPERTENSION GRADE 3	2020-10-07 (30)/ 2020-10-07 (30)	Yes/ No/ No	3	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912163; Age (years): 43; Sex: M; Race: OTHER: (b) (6)							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-13 09:55 (28)/ 2020-10-13 10:07 (28)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3922067; Age (years): 77; Sex: F; Race: WHITE							
Psychiatric disorders/ Confusional state/ CONFUSION	2020-09-07 (7)/ 2020-09-09 (9)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-09)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932005; Age (years): 79; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Hiatus hernia/ HIATAL HERNIA	2020-10-20 (30)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-20/ 2020-10-22)	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932083; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 POSITIVE	2020-11-14 (38)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-16/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3932182; Age (years): 62; Sex: F; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Cervical spinal stenosis/ C5-C6 SEVERE LEFT CANAL STENOSIS	2020-10-26 (7)/ 2020-11-17 (29)	Yes/ Yes/ No	3	Yes/3 (2020-10-26/ 2020-10-28)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952033; Age (years): 52; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Food poisoning/ FOOD POISONING	2020-09-23 (22)/ 2020-09-30 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-23/ 2020-09-30)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3952033; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-10-06 (35)/ 2020-10-25 (54)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Cardiac disorders/ Pericarditis/ PERICARDITIS	2020-10-31 (60)/ 2020-11-03 (63)	Yes/ No/ No	3	Yes/3 (2020-10-31/ 2020-11-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
		Yes/ Yes/ No	3	Yes/3 (2020-10-31/ 2020-11-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3952040; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED GRADE 3 BP	2020-09-03 14:56 (1)/ 2020-09-04 (2)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982031; Age (years): 86; Sex: F; Race: WHITE							
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-09-10 (15)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-25/ 2020-09-26)/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3992010; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID 19	2020-11-12 (23)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3992040; Age (years): 28; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 (21)/ 2020-10-29 (34)	Yes/ Yes/ Yes	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012023; Age (years): 29; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE, LEFT ARM	2020-08-25 21:00 (1)/ 2020-09-02 (9)	Yes/ Yes/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012053; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE, LEFT ARM	2020-08-06 16:00 (1)/ 2020-08-26 (21)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012098; Age (years): 60; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Colitis/ COLITIS	2020-09-24 (17)/ 2020-09-30 (23)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012098; Age (years): 60; Sex: F; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ EXACERBATION OF DIASTOLIC CHF	2020-09-29 (22)/ 2020-10-12 (35)	Yes/ Yes/ No	3	Yes/3 (2020-09-29/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Clostridium difficile infection/ CLOSTRICFIUM DIFFICILE	2020-09-29 (22)/ 2020-10-25 (48)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022020; Age (years): 63; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Intraductal proliferative breast lesion/ DUCTAL CARCINOMA INSITUU LEFT BREAST	2020-10-16 (54)/ 2020-11-13 (82)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022033; Age (years): 39; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-31 (68)/ 2020-11-01 (69)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-31 (68)/ 2020-11-02 (70)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022038; Age (years): 73; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-07-29 12:08 (2)/ 2020-08-05 09:00 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022038; Age (years): 73; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER	2020-07-30 (3)/ 2020-08-05 (9)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022052; Age (years): 55; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Oesophageal carcinoma/ ESOPHAGEAL CANCER	2020-10-15 (35)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022062; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-04 (7)/ 2020-08-07 (10)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022062; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-04 (7)/ 2020-08-12 (15)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022103; Age (years): 59; Sex: F; Race: WHITE							
Investigations/ Hepatic enzyme increased/ ELEVATED LIVER ENZYMES	2020-08-17 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022167; Age (years): 21; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Gastritis/ ACUTE GASTITIS	2020-10-14 (31)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042265; Age (years): 46; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ SEVERE NAUSEA	2020-10-06 (20)/ 2020-10-09 (23)	Yes/ Yes/ No	3	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042265; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ SEVERE HEADACHE	2020-10-06 (20)/ 2020-10-10 (24)	Yes/ Yes/ No	3	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3052028; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN NOS	2020-08-05 (7)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-05/ 2020-08-06)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3052262; Age (years): 35; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Adverse drug reaction/ ADVERSE EFFECT OF DRUG	2020-09-18 19:00 (1)/ 2020-09-24 08:00 (6)	Yes/ Yes/ No	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062151; Age (years): 72; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural nausea/ POST OP NAUSEA RECURRENT	2020-10-20 (47)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062151; Age (years): 72; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ POST OP PAIN	2020-10-20 (47)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ GENERALIZED PAIN	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Pain/ GENERALIZED PAIN	2020-10-27 (35)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Alcohol poisoning/ ACUTE ALCOHOL INTOXICATION	2020-10-27 (35)/ 2020-10-28 (36)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN, GENERALIZED	2020-10-28 (36)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	2020-10-28 (36)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3082020; Age (years): 36; Sex: F; Race: WHITE							
Hepatobiliary disorders/ Cholelithiasis/ GALLSTONES	2020-08-15 (4)/ 2020-08-25 (14)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082081; Age (years): 66; Sex: M; Race: WHITE							
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2020-10-02 (12)/ 2020-10-19 (29)	Yes/ Yes/ No	3	Yes/3 (2020-10-02/ 2020-10-05)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3102061; Age (years): 72; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION WITH RVR	2020-08-20 (22)/ 2020-08-23 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-20 (22)/ 2020-08-23 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypertensive urgency/ HYPERTENSIVE URGENCY	2020-08-20 (22)/ 2020-08-23 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122010; Age (years): 62; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Lung cancer metastatic/ RECURRENCE OF THROAT CANCER WITH METASTASES TO LUNGS	2020-08-12 (17)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3122086; Age (years): 51; Sex: M; Race: WHITE							
Nervous system disorders/ Migraine/ COMPLICATED MIGRAINE	2020-08-20 (24)/ 2020-08-23 (27)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122128; Age (years): 64; Sex: M; Race: WHITE							
Nervous system disorders/ Movement disorder/ DIFFICULTY RAISING LEFT ARM	2020-07-30 00:00 (1)/ 2020-08-01 23:59 (4)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3142185; Age (years): 73; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Volvulus/ INTESTINAL TORSION	2020-09-18 (3)/ 2020-09-26 (11)	Yes/ Yes/ No	3	Yes/3 (2020-09-18/ 2020-09-26)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3142268; Age (years): 60; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCER	2020-10-22 (23)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-22/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152342; Age (years): 68; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ LEFT KIDNEY STONE 4MM	2020-10-07 (15)/ 2020-10-10 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162003; Age (years): 75; Sex: F; Race: WHITE							
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-09-09 (17)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162007; Age (years): 68; Sex: F; Race: WHITE							
Nervous system disorders/ Cerebrovascular accident/ MILD CEREBROVASCULAR ACCIDENT	2020-07-30 (4)/ 2020-07-31 (5)	Yes/ Yes/ No	3	Yes/3 (2020-07-30/ 2020-07-31)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172333; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Salpingitis/ BILATERAL ACUTE SALPINGITIS	2020-11-09 (47)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-09/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192486; Age (years): 73; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ DEEP VEIN THROMBOSIS & PULMONARY EMBOLISM	2020-11-02 (41)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Surgical and medical procedures/ Transfusion/ BLOOD TRANSFUSION	2020-11-02 (41)/ 2020-11-04 (43)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED WITH SEQUELAE: COLONOSCOPY
Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GI BLEED	2020-11-02 (41)/ 2020-11-08 (47)	Yes/ Yes/ No	3	Yes/3 (2020-11-02/ 2020-11-08)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED WITH SEQUELAE: COLONOSCOPY

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202191; Age (years): 77; Sex: M; Race: WHITE							
Infections and infestations/ Wound infection/ RIGHT ELBOW WOUND INFECTION	2020-10-27 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3212013; Age (years): 45; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Uterine haemorrhage/ ABNORMAL UTERINE BLEEDING	2020-08-27 (25)/ 2020-08-28 (26)	Yes/ Yes/ No	3	Yes/3 (2020-08-27/ 2020-08-28)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Uterine haemorrhage/ WORSENING OF ABNORMAL UTERINE BLEEDING	2020-09-22 (51)/ 2020-09-22 (51)	Yes/ No/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212028; Age (years): 67; Sex: M; Race: WHITE							
Cardiac disorders/ Acute coronary syndrome/ ACUTE CORONARY SYNDROME (NON ST ELEVATED MYOCARDIAL INFARCTION)	2020-10-20 (50)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-23/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212158; Age (years): 35; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY IPSILATERAL TO INJECTION SITE	2020-08-18 (6)/ 2020-08-21 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222013; Age (years): 68; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-11-14 (72)/ 2020-11-16 (74)	Yes/ Yes/ No	3	Yes/3 (2020-11-14/ 2020-11-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222054; Age (years): 54; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE/ARM REDNESS	2020-08-21 (14)/ 2020-08-26 (19)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222061; Age (years): 71; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Breast mass/ MASS ON RIGHT BREAST POSSITIVE FOR CANCER	2020-09-04 (26)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222091; Age (years): 59; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-09-10 (31)/ 2020-09-22 (43)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222154; Age (years): 53; Sex: M; Race: WHITE							
Cardiac disorders/ Ventricular tachycardia/ VENTRICULAR TACHYCARIA	2020-10-23 (40)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222296; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-23 00:00 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222299; Age (years): 57; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2020-10-03 (11)/ 2020-10-05 (13)	Yes/ Yes/ No	3	Yes/3 (2020-10-03/ 2020-10-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222316; Age (years): 79; Sex: M; Race: WHITE							
Immune system disorders/ Type IV hypersensitivity reaction/ DELAYED TYPE-HYPERSENSITIVITY	2020-08-31 (8)/ 2020-09-04 (12)	Yes/ Yes/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222452; Age (years): 80; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Cervical vertebral fracture/ C3 CERVICAL FRACTURE	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222452; Age (years): 80; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Facial bones fracture/ NASAL FRACTURE	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Skin laceration/ FACIAL LACERATION	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Subdural haematoma/ SUBDURAL HEMATOMA	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Fall/ FALL	2020-10-26 (25)/ 2020-10-30 (29)	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232121; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-07 (11)/ 2020-09-17 (21)	Yes/ Yes/ No	3	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242017; Age (years): 64; Sex: M; Race: WHITE							
Infections and infestations/ Bronchitis/ ACUTE BRONCHITIS	2020-10-17 (40)/ 2020-10-27 (50)	Yes/ Yes/ No	3	Yes/3 (2020-10-19/ 2020-10-21)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242041; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteonecrosis/ WORSENING OF BILATERAL FEMORAL HEAD NECROSIS	2020-11-18 (70)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242231; Age (years): 76; Sex: F; Race: WHITE							
Vascular disorders/ Aortic aneurysm/ WORSENING AORTIC ANEURYSM	2020-10-08 (14)/ 2020-10-28 (34)	Yes/ Yes/ No	3	Yes/3 (2020-10-27/ 2020-11-06)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242231; Age (years): 76; Sex: F; Race: WHITE							
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-10-15 (21)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242269; Age (years): 77; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ CLOSED FRACTURE OF BASE OF 5TH METATARSAL BONE, LEFT FOOT	2020-10-02 (3)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242314; Age (years): 75; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATIC ADENOCARCINOMA (GLEASON SCORE 3+4+=7)	2020-11-06 (29)/ Ongoing	Yes/ Yes/ No	3	Yes/2	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242321; Age (years): 35; Sex: F; Race: MULTIPLE: (b) (6)							
Gastrointestinal disorders/ Umbilical hernia/ UMBILICAL HERNIA	2020-10-13 10:00 (1)/ 2020-10-17 (6)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242370; Age (years): 28; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Schizoaffective disorder/ WORSENING OF SCHIZOAFFECTIVE DISORDER	2020-09-29 (7)/ 2020-10-03 (11)	Yes/ Yes/ No	3	Yes/2/3 (2020-09-29/ 2020-10-03)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252127; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-10-28 (51)/ 2020-10-29 (52)	Yes/ Yes/ No	3	Yes/3 (2020-10-28/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252166; Age (years): 50; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Thyroid cancer metastatic/ METASTATIC PAPILLARY THYROID CARCINOMA	2020-09-22 (13)/ 2020-10-30 (51)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Endocrine disorders/ Thyroid disorder/ THYROIDECTOMY	2020-11-01 (53)/ 2020-11-01 (53)	Yes/ Yes/ No	3	Yes/3 (2020-10-30/ 2020-11-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252516; Age (years): 40; Sex: M; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Colitis/ COLITIS	2020-09-30 00:00 (9)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-30/ 2020-10-08)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252516; Age (years): 40; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-30 00:00 (9)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-30/ 2020-10-08)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272027; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN IN POSTERIOR NECK	2020-09-29 (6)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3272123; Age (years): 37; Sex: F; Race: WHITE							
Immune system disorders/ Seasonal allergy/ SEASONAL ALLERGIES	2020-08-23 (12)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272124; Age (years): 55; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain lower/ LEFT LOWER QUADRANT PAIN	2020-10-15 (36)/ 2020-10-15 (36)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Flank pain/ LEFT FLANK PAIN	2020-10-15 (36)/ 2020-10-15 (36)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3272149; Age (years): 28; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (GENERALIZED)	2020-11-01 (52)/ 2020-11-14 (65)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272149; Age (years): 28; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-01 (52)/ 2020-11-21 (72)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272169; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-16 (1)/ 2020-10-01 (16)	Yes/ No/ Yes	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Rectal prolapse/ RECTAL PROLAPSE REPAIR COMPLICATION DUE TO CONSTIPATION	2020-11-05 (51)/ 2020-11-07 (53)	Yes/ Yes/ No	3	Yes/3 (2020-11-05/ 2020-11-07)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272320; Age (years): 62; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-02 (43)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272327; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-24 (33)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERLAIZED MUSCLE ACHES	2020-10-07 (13)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-09 (15)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-10-09 (15)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272343; Age (years): 46; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-09 (18)/ 2020-09-20 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-09 (18)/ 2020-09-20 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-15 (24)/ 2020-09-20 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292023; Age (years): 80; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Diabetic ketoacidosis/ DIABETIC KETOACIDOSIS	2020-10-22 (52)/ 2020-10-26 (56)	Yes/ Yes/ No	3	Yes/3 (2020-10-22/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292055; Age (years): 49; Sex: F; Race: WHITE							
Hepatobiliary disorders/ Cholelithiasis/ CHOLELITHIASIS	2020-08-16 (9)/ 2020-08-27 (20)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3292057; Age (years): 65; Sex: F; Race: WHITE							
Vascular disorders/ Hypertensive emergency/ HYPERTENSIVE EMERGENCY	2020-10-01 (29)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292103; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Subdural haematoma/ SUBDURAL HEMATOMA	2020-11-14 (71)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-15/ 2020-11-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3292145; Age (years): 67; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal septum deviation/ DEVIATED SEPTUM	2020-10-01 (20)/ 2020-10-19 (38)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292304; Age (years): 35; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Large intestine perforation/ PERFORATED COLON	2020-10-04 (13)/ 2020-10-06 (15)	Yes/ Yes/ No	3	Yes/3 (2020-10-04/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2020-10-07 (16)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-04/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292324; Age (years): 66; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Femur fracture/ R BROKEN FEMUR	2020-11-03 (41)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292365; Age (years): 58; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Invasive lobular breast carcinoma/ INVASIVE LOBULAR BREAST CARCINOMA	2020-10-08 (13)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312006; Age (years): 62; Sex: M; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED BLOOD (SYSTOLIC) PRESSURE	2020-08-10 13:27 (1)/ 2020-09-07 11:07 (28)	Yes/ No/ No	3	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312030; Age (years): 78; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS (MACULAR NON-URTICARIAL) AT INJECTION SITE (LEFT ARM)	2020-09-09 (3)/ 2020-10-18 (42)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312051; Age (years): 59; Sex: M; Race: OTHER: (b) (6)							
Investigations/ Blood pressure systolic increased/ SYSTOLIC BLOOD PRESSURE INCREASE	2020-08-12 14:50 (1)/ 2020-08-12 15:00 (1)	Yes/ No/ No	3	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312077; Age (years): 47; Sex: M; Race: WHITE							
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BLOOD PRESSURE	2020-10-09 (29)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312077; Age (years): 47; Sex: M; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-09 (29)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312083; Age (years): 76; Sex: F; Race: WHITE							
Vascular disorders/ Systolic hypertension/ EXACERBATION OF HYPERTENSION (ELEVATED SYSTOLIC BLOOD PRESSURE)	2020-08-14 14:30 (1)/ 2020-09-11 12:17 (28)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Systolic hypertension/ EXACERBATION OF HYPERTENSION (ELEVATED SYSTOLIC BLOOD PRESSURE)	2020-10-09 (29)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312092; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ MACULAR NON-UTICARIAL REDNESS AT INJECTION SITE	2020-09-11 (1)/ 2020-09-21 (11)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312109; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE (MACULAR/NON-UTICARIAL)	2020-09-15 (2)/ 2020-09-22 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312186; Age (years): 74; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-26 (40)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312249; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Gastrointestinal infection/ INTESTINAL INFECTION	2020-09-23 (31)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312253; Age (years): 73; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic decreased/ DECREASED SYSTOLIC BLOOD PRESSURE	2020-10-06 (16)/ 2020-10-06 (16)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312367; Age (years): 58; Sex: M; Race: WHITE							
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BLOOD PRESSURE	2020-09-25 09:14 (28)/ 2020-09-25 10:41 (28)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312485; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-04 (35)/ 2020-11-04 (35)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312499; Age (years): 63; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-29 (29)/ 2020-10-29 (29)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312596; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ LOWER RIGHT BACK TOOTH INFECTION	2020-09-30 (21)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312602; Age (years): 77; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-08 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322302; Age (years): 37; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Wrist fracture/ RIGHT SCAPHOID FRACTURE	2020-10-22 (15)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322329; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling face/ FACIAL SWELLING	2020-10-17 (3)/ 2020-10-22 (8)	Yes/ Yes/ No	3	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322353; Age (years): 73; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE ADENOCARCINOMA	2020-10-16 (4)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352070; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tibia fracture/ LEFT DISTAL TIBIA FRACTURE	2020-09-25 11:00 (17)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3352084; Age (years): 58; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-06 (29)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	
Subject ID: US3352299; Age (years): 48; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH SKIN ERUPTION	2020-11-11 (44)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3352585; Age (years): 40; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-15 18:41 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352594; Age (years): 31; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-10-22 18:00 (1)/ 2020-10-25 (4)	Yes/ Yes/ No	3	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362034; Age (years): 50; Sex: M; Race: WHITE							
Eye disorders/ Retinal detachment/ RETINAL DETACHMENT OF LEFT EYE	2020-11-06 (60)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3362097; Age (years): 53; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSIVE EPISODE	2020-10-07 (30)/ 2020-10-08 (31)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362116; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ WORSENING OF CHRONIC NECK PAIN	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382134; Age (years): 33; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-30 (3)/ 2020-08-30 (3)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3382267; Age (years): 49; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ GENERALIZED RASH	2020-10-13 (2)/ Ongoing	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382284; Age (years): 45; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Gastric cancer/ GASTRIC CANCER	2020-10-29 (44)/ Ongoing	Yes/ Yes/ No	3	Yes/2/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3392120; Age (years): 63; Sex: M; Race: WHITE							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-24 (25)/ 2020-10-26 (27)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3392149; Age (years): 30; Sex: M; Race: WHITE							
Infections and infestations/ Hepatitis A/ HEPATITIS A	2020-09-24 (23)/ 2020-09-25 (24)	Yes/ Yes/ No	3	Yes/3 (2020-09-24/ 2020-09-25)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3392192; Age (years): 50; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Tendon injury/ WRIST TENDON LACERATION, RIGHT	2020-09-15 (7)/ 2020-09-22 (14)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3392236; Age (years): 48; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pleurisy/ PLEURISY	2020-10-13 (7)/ 2020-10-16 (10)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3392258; Age (years): 55; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ FOOT FRACTURE	2020-10-09 12:00 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3392278; Age (years): 60; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE	2020-10-12 08:30 (28)/ 2020-10-12 (29)	Yes/ No/ No	3	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402212; Age (years): 79; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ WORSENING SPINAL STENOSIS	2020-08-23 (20)/ 2020-09-29 (57)	Yes/ Yes/ No	3	Yes/3 (2020-08-23/ 2020-08-25)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3402284; Age (years): 58; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-09-22 (13)/ 2020-09-23 (14)	Yes/ Yes/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422135; Age (years): 67; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ SPINAL STENOSIS	2020-10-06 (12)/ 2020-10-08 (14)	Yes/ Yes/ No	3	Yes/3 (2020-10-06/ 2020-10-08)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432016; Age (years): 76; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GERD	2020-10-22 (51)/ 2020-10-24 (53)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432083; Age (years): 24; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	2020-09-05 (20)/ 2020-09-08 (23)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432094; Age (years): 76; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Meningioma/ CRANIOPLASTY AND CRANIECTOMY FOR MENINGIOMA	2020-11-23 (75)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-23/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432118; Age (years): 47; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC B/P	2020-09-14 (1)/ 2020-09-15 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432229; Age (years): 24; Sex: F; Race: WHITE							
Psychiatric disorders/ Intentional self-injury/ SELF- INJURIOUS BEHAVIOR	2020-10-17 (30)/ 2020-10-30 (43)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-30)/6	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432389; Age (years): 92; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC B/P 191 MMHG MAX	2020-09-29 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432392; Age (years): 68; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ BENIGN PROSTATIC HYPERPLASIA (BPH) S/P TRANSURETHRAL RESECTION OF THE PROSTATE (TURP)	2020-10-19 (21)/ 2020-10-20 (22)	Yes/ Yes/ No	3	Yes/3 (2020-10-19/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432468; Age (years): 71; Sex: F; Race: WHITE							
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BLOOD PRESSURE 168 MM/HG	2020-10-06 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3432487; Age (years): 66; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE 162	2020-10-09 09:26 (1)/ 2020-10-10 (2)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432516; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Burns second degree/ SECOND DEGREE BURNS (FACE, R EAR, R HAND)	2020-11-02 (18)/ 2020-11-18 (34)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432571; Age (years): 39; Sex: M; Race: ASIAN							
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BP	2020-10-27 07:13 (28)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-27 07:13 (28)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432627; Age (years): 33; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Hernia/ HERNIA S/P LEFT INGUINAL HERNIA REPAIR	2020-11-23 (6)/ 2020-11-24 (7)	Yes/ Yes/ No	3	Yes/3 (2020-11-23/ 2020-11-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3442002; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING OF HTN	2020-09-10 10:38 (1)/ 2020-10-05 11:00 (26)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442031; Age (years): 55; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT CALF PAIN	2020-11-01 (42)/ 2020-11-12 (53)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442031; Age (years): 55; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2020-11-03 (44)/ 2020-11-04 (45)	Yes/ Yes/ No	3	Yes/3 (2020-11-03/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Deep vein thrombosis/ DEEP VEIN THROMBOSIS (LEFT LEG)	2020-11-03 (44)/ 2020-11-04 (45)	Yes/ Yes/ No	3	Yes/3 (2020-11-03/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-04 (45)/ 2020-11-12 (53)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442113; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-09-02 21:00 (2)/ 2020-09-04 10:51 (3)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3442237; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-11-09 (26)/ 2020-11-16 (33)	Yes/ No/ No	3	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462076; Age (years): 28; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT WRIST SPRAIN	2020-09-07 (4)/ 2020-09-22 (19)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472089; Age (years): 48; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Stab wound/ PARTICIPANT WAS STABBED ON 11/09/2020	2020-11-09 (12)/ 2020-11-09 (12)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482048; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Colitis/ ACUTE COLITIS	2020-10-27 (47)/ 2020-11-19 (70)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Campylobacter gastroenteritis/ CAMPYLOBACTER ENTERITIS	2020-11-04 (55)/ 2020-11-19 (70)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3482064; Age (years): 71; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash macular/ NON-URTICARIAL MACULAR RASH WITH BLANCHING ERYTHEMA ON LEFT DELTOID	2020-08-25 (9)/ 2020-09-04 (19)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482070; Age (years): 53; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES PAST DAY 7 OF REACTO PERIOD	2020-09-15 08:00 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3482080; Age (years): 70; Sex: M; Race: WHITE							
Nervous system disorders/ Sciatica/ LEFT SIDED SCIATICA FLARE-UP	2020-10-07 (22)/ 2020-10-15 (30)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482090; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ NON-URTICARIAL, MACULAR, REDNESS ON LEFT DELTOID AT THE INJECTION SITE	2020-09-16 15:51 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482090; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-17 12:05 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3482254; Age (years): 61; Sex: M; Race: WHITE							
Nervous system disorders/ Post herpetic neuralgia/ NEUROPATHIC PAIN/POST HERPETIC NEURALGIA LEFT CHEST	2020-09-16 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482284; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN	2020-11-16 (32)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-18/)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492015; Age (years): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-15 (23)/ 2020-10-15 (23)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492022; Age (years): 74; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Gout/ GOUT	2020-10-23 (29)/ 2020-11-13 (50)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492066; Age (years): 40; Sex: M; Race: WHITE							
Infections and infestations/ Skin infection/ RIGHT INDEX FINGER SKIN INFECTION	2020-11-09 (41)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492069; Age (years): 85; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION OF UNKNOWN ETIOLOGY- FEVER, NASAL CONGESTION, GENERALIZED MUSCLE AND BODY ACHES, FATIGUE	2020-10-05 (32)/ 2020-10-08 (35)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492070; Age (years): 31; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA EXACERBATION	2020-09-16 (13)/ 2020-09-16 (13)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492078; Age (years): 93; Sex: M; Race: WHITE							
Vascular disorders/ Haematoma/ HEMATOMA OF THE R LEG	2020-11-03 (33)/ 2020-11-11 (41)	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3492095; Age (years): 38; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-28 (21)/ 2020-10-20 (43)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Proctitis chlamydial/ CHLAMYDIA PROSTATITIS	2020-10-16 (11)/ 2020-10-23 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492102; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Immune system disorders/ Seasonal allergy/ EXACERBATION OF SEASONAL ALLERGIES - NASAL CONGESTION, RUNNY NOSE	2020-10-07 (29)/ 2020-10-21 (43)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492123; Age (years): 53; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-04 (24)/ 2020-10-04 (24)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492155; Age (years): 84; Sex: M; Race: WHITE							
Vascular disorders/ Peripheral artery occlusion/ PERIPHERAL VASCULAR DISEASE WITH ACUTE BLOCKAGE	2020-09-28 (14)/ 2020-10-23 (39)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492212; Age (years): 43; Sex: F; Race: OTHER: (b) (6)							
Reproductive system and breast disorders/ Ovarian cyst/ OVARIAN CYST	2020-11-15 (31)/ 2020-11-18 (34)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502058; Age (years): 44; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY ADENOPATHY - IPSILATERAL	2020-09-28 (4)/ Ongoing	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3512006; Age (years): 78; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA ON SCALP	2020-09-16 (15)/ 2020-09-29 (28)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512008; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INJECTION SITE INDURATION	2020-09-02 17:20 (1)/ 2020-09-13 13:01 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-02 17:20 (1)/ 2020-09-13 13:01 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512025; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Malaise/ MALAISE	2020-09-03 18:30 (1)/ 2020-09-17 06:00 (14)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512047; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-21 (10)/ 2020-08-27 (16)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE	2020-08-21 (10)/ 2020-08-28 (17)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512051; Age (years): 29; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-11 23:30 (2)/ 2020-09-12 07:30 (2)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512177; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LEG MUSCLE ACHES	2020-09-25 22:00 (1)/ 2020-10-09 08:30 (14)	Yes/ No/ Yes	3	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-01 (7)/ 2020-10-04 (10)	Yes/ No/ Yes	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512193; Age (years): 77; Sex: F; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-10-27 (26)/ Ongoing	Yes/ Yes/ Yes	3	Yes/3 (2020-10-27/ 2020-10-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512261; Age (years): 59; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Diverticulum/ DIVERTICULOSIS	2020-10-17 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512273; Age (years): 75; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ BILATERAL CHEST ERYTHEMA PATCHES; NON-URTICARIAL;	2020-10-01 (15)/ 2020-10-03 (17)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512287; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Abscess/ HIDRADENITIS SUPPURITIVA ABSCESS EXACERBATION (RIGHT ARM: 10 ABSCESSES) (LEFT AXILLARY REGION: 1 ABSCESS) (ABDOMEN: 1 ABSCESS)	2020-10-18 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3512288; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-08 (8)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522002; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Renal and urinary disorders/ Nephrolithiasis/ FLANK PAIN-PASSING KIDNEY STONE	2020-10-07 (36)/ 2020-10-07 (36)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522108; Age (years): 68; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-15 (3)/ 2020-08-15 (3)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522160; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER OF 101.5	2020-09-16 14:00 (2)/ 2020-09-17 12:00 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522191; Age (years): 34; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (3)/ 2020-09-18 (3)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522299; Age (years): 58; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 (9)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522349; Age (years): 54; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-11-01 (40)/ 2020-11-02 (41)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522664; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RIGHT DELTOID MACULAR, NON-URTICARIAL REDNESS AT INJECTION SITE 120MM BY 86MM OBLONG	2020-09-23 (13)/ 2020-09-25 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522665; Age (years): 76; Sex: F; Race: WHITE							
Nervous system disorders/ Lumbar radiculopathy/ LUMBAR RADICULOPATHY	2020-10-23 (43)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3532083; Age (years): 50; Sex: F; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE	2020-09-26 08:00 (1)/ 2020-09-26 11:00 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532093; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA.	2020-09-22 (1)/ 2020-10-17 (26)	Yes/ No/ Yes	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532108; Age (years): 66; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ OPTICAL HEADACHE	2020-09-24 (2)/ 2020-09-24 (2)	Yes/ Yes/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532149; Age (years): 66; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiomyopathy/ CATECHOLAMINE CARDIOMYOPATHY	2020-10-19 (27)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3532152; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Head injury/ HEAD INJURY	2020-10-03 (10)/ 2020-10-15 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Skin laceration/ FOREHEAD LACERATION	2020-10-03 (10)/ 2020-10-15 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532192; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Renal cancer/ KIDNEY CANCER	2020-10-09 (4)/ Ongoing	Yes/ Yes/ No	3	Yes/2/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542206; Age (years): 71; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-10 17:02 (1)/ 2020-09-22 (13)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542241; Age (years): 64; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Plasma cell myeloma/ WORSENING MULTIPLE MYELOMA	2020-10-20 (7)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542276; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL ELBOWS AND RIGHT KNEE ARTHRALGIAS	2020-09-23 01:00 (1)/ 2020-10-06 (15)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIAS	2020-09-23 01:00 (1)/ 2020-10-06 (15)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542309; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Subarachnoid haemorrhage/ SUBARACHNOID HEMORRHAGE	2020-11-13 (17)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-13/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Syncope/ SYNCOPE	2020-11-13 (17)/ 2020-11-13 (17)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542332; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Seizure/ EXACERBATION OF SEIZURE DISORDER	2020-11-07 (30)/ 2020-11-08 (31)	Yes/ Yes/ No	3	Yes/3 (2020-11-07/ 2020-11-08)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552024; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN, NON-SPECIFIED	2020-08-24 (12)/ 2020-09-11 (30)	Yes/ Yes/ No	3	Yes/3 (2020-08-29/ 2020-08-30)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552101; Age (years): 66; Sex: M; Race: WHITE							
Nervous system disorders/ Cervical radiculopathy/ CERVICAL RADICULOPATHY	2020-10-21 (36)/ 2020-11-06 (52)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552189; Age (years): 21; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Meniscus injury/ LEFT KNEE MENISCUS TEAR	2020-10-27 (63)/ 2020-11-05 (72)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3552191; Age (years): 66; Sex: F; Race: WHITE							
Endocrine disorders/ Hyperthyroidism/ HYPERTHYROIDISM	2020-10-26 (34)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3552371; Age (years): 56; Sex: F; Race: WHITE							
Investigations/ Hepatic enzyme increased/ ELEVATED LIVER ENZYMES	2020-09-16 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Ankle fracture/ FRACTURED LEFT ANKLE	2020-09-16 (9)/ 2020-11-19 (73)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552410; Age (years): 67; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING BACK PAIN	2020-11-21 (44)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3552416; Age (years): 52; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-06 (26)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3572270; Age (years): 64; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ SEVERE ITCHING	2020-10-22 (14)/ 2020-10-24 (16)	Yes/ Yes/ No	3	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ RASH	2020-10-22 (14)/ 2020-10-24 (16)	Yes/ Yes/ No	3	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582002; Age (years): 69; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-13 (28)/ 2020-10-14 (29)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582027; Age (years): 73; Sex: M; Race: WHITE							
Vascular disorders/ Systolic hypertension/ SYSTOLIC HYPERTENSION	2020-08-21 16:40 (1)/ 2020-08-28 14:15 (7)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582045; Age (years): 55; Sex: M; Race: WHITE							
Vascular disorders/ Systolic hypertension/ SYSTOLIC HYPERTENSION	2020-10-20 (28)/ 2020-11-01 (40)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582070; Age (years): 68; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ BACK SPASMS	2020-09-25 (2)/ 2020-09-28 (5)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582074; Age (years): 62; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-30 (33)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3582114; Age (years): 40; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT (INJECTION SIDE) AXILLARY LYMPHADENOPATHY	2020-09-08 18:00 (1)/ 2020-10-06 23:59 (29)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582121; Age (years): 51; Sex: M; Race: MULTIPLE: (b) (6)							
Vascular disorders/ Systolic hypertension/ SYSTOLIC HYPERTENSION	2020-09-09 10:13 (1)/ 2020-09-09 19:00 (1)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582140; Age (years): 75; Sex: F; Race: MULTIPLE: (b) (6)							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-11-09 (33)/	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582167; Age (years): 29; Sex: M; Race: WHITE							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-09-30 16:35 (1)/ 2020-10-26 16:35 (27)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3592232; Age (years): 79; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Femoral neck fracture/ RIGHT SUBCAPITAL FEMORAL NECK FRACTURE, DISPLACED GARDEN III	2020-08-25 (6)/ 2020-10-05 (47)	Yes/ Yes/ No	3	Yes/3 (2020-08-25/ 2020-08-28)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3592247; Age (years): 87; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-11-10 (46)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3602027; Age (years): 61; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament injury/ LIGAMENT TEAR (LEFT KNEE)	2020-09-28 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3612004; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RETICULATE MACULAR ERYTHEMA AT INJECTION SITE, RIGHT ARM	2020-09-07 (8)/ 2020-09-11 (12)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3612013; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Oedema peripheral/ RIGHT LEG EDEMA	2020-09-05 (3)/ 2020-09-07 (5)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622004; Age (years): 77; Sex: M; Race: ASIAN							
Injury, poisoning and procedural complications/ Fibula fracture/ LEFT FIBULA FRACTURE	2020-08-24 (15)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622192; Age (years): 69; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Diabetes mellitus inadequate control/ UNCONTROLLED DIABETES	2020-09-18 (3)/ 2020-11-06 (52)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622217; Age (years): 65; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-09-28 (7)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3632021; Age (years): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-22 12:16 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632027; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ LEFT ARM (NON-URTICARIAL) INJECTION SITE RED PATCH	2020-09-09 (10)/ 2020-09-11 (12)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632038; Age (years): 74; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-05 11:00 (1)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632052; Age (years): 61; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-08 11:38 (1)/ 2020-10-06 (29)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632053; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-08 11:55 (1)/ 2020-10-06 (29)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632065; Age (years): 34; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ POST-DOSE HIGH BLOOD PRESSURE	2020-10-05 15:21 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632095; Age (years): 50; Sex: M; Race: UNKNOWN							
Investigations/ Blood pressure increased/ POST-DOSE ELEVATED BLOOD PRESSURE	2020-10-15 16:29 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632100; Age (years): 69; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ BROKEN TOE	2020-09-28 (7)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthralgia/ HIP PAIN (RIGHT)	2020-10-14 (23)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN (WORSENING)	2020-10-14 (23)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632101; Age (years): 24; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	2020-10-22 (3)/ 2020-10-23 (4)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3642250; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH FROM VACCINE #1	2020-09-26 (8)/ 2020-09-29 (11)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3642295; Age (years): 23; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-03 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3642312; Age (years): 46; Sex: F; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-10-14 (2)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662121; Age (years): 39; Sex: F; Race: OTHER: (b) (6)							
Injury, poisoning and procedural complications/ Skin laceration/ LASCERATED LEFT THUMB	2020-10-08 (18)/ 2020-10-08 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Limb injury/ PAIN IN CUT FINGER	2020-10-08 (18)/ 2020-10-11 (21)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672045; Age (years): 35; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-09 17:24 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3672092; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (L)	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672093; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT SITE OF INJECTION (LEFT ARM)	2020-08-23 (11)/ 2020-08-25 (13)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3682017; Age (years): 41; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Colitis/ COLITIS	2020-09-21 (27)/ 2020-10-13 (49)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	2020-09-21 (27)/ 2020-10-13 (49)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692020; Age (years): 50; Sex: F; Race: WHITE							
Eye disorders/ Scleritis/ EYE REDNESS (SCLERITIS)	2020-09-04 (7)/ 2020-09-07 (10)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692062; Age (years): 71; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-05 13:54 (1)/ 2020-10-01 13:08 (26)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692080; Age (years): 34; Sex: M; Race: ASIAN							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-09-09 16:00 (1)/ 2020-10-06 (28)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692083; Age (years): 51; Sex: M; Race: WHITE							
Infections and infestations/ Conjunctivitis/ PINK EYE BILATERAL	2020-09-28 (20)/ 2020-11-03 (56)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692086; Age (years): 37; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-09-12 (3)/ 2020-09-21 (12)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692090; Age (years): 67; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-04 (28)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692144; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-19 13:40 (1)/ 2020-10-20 13:55 (2)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692157; Age (years): 49; Sex: F; Race: NOT REPORTED							
Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2020-10-30 (11)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692160; Age (years): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ THROAT PAIN FROM INCUBATION	2020-10-13 (16)/ 2020-10-16 (19)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692174; Age (years): 28; Sex: M; Race: OTHER: (b) (6)							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-29 10:19 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692197; Age (years): 42; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-22 (8)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692202; Age (years): 21; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-11-01 (11)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3702010; Age (years): 74; Sex: M; Race: UNKNOWN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-04 (1)/ 2020-09-11 (8)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702010; Age (years): 74; Sex: M; Race: UNKNOWN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-05 20:22 (2)/ 2020-09-11 (8)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3712193; Age (years): 59; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ GRADE 3 HYPERTENSION	2020-11-12 11:20 (28)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3722163; Age (years): 24; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-10 10:00 (1)/ 2020-09-10 22:00 (2)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722187; Age (years): 71; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN IN THE INJECTION SITE	2020-09-10 15:00 (30)/ 2020-09-10 23:00 (31)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722224; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722239; Age (years): 20; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE GRADE 3	2020-09-10 17:00 (1)/ 2020-09-11 22:00 (2)	Yes/ No/ No	3	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-10 17:00 (1)/ 2020-09-11 22:00 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722258; Age (years): 35; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-14 17:00 (1)/ 2020-09-16 22:00 (3)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722258; Age (years): 35; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-09-15 11:00 (1)/ 2020-09-15 23:59 (2)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-15 11:00 (1)/ 2020-09-16 22:00 (3)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722320; Age (years): 30; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 (9)/ 2020-09-24 (9)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722320; Age (years): 30; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-24 (9)/ 2020-09-24 (9)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-09-24 (9)/ 2020-09-24 (9)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-24 (9)/ 2020-09-24 (9)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (9)/ 2020-09-24 (9)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722342; Age (years): 60; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 (9)/ 2020-09-23 (9)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732071; Age (years): 69; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-09 (29)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732132; Age (years): 73; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Rectal cancer/ RECTAL CARCINOMA	2020-09-01 (12)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732167; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-25 15:43 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732322; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER (103 F)	2020-11-03 (28)/ 2020-11-03 (28)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742007; Age (years): 60; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-14 08:15 (28)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	
Subject ID: US3742029; Age (years): 53; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-18 08:38 (1)/ 2020-10-19 07:30 (31)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742075; Age (years): 40; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION EXACERBATION	2020-08-25 10:52 (1)/ 2020-09-22 08:35 (28)	Yes/ No/ No	3	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742105; Age (years): 70; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ KNEE PAIN	2020-10-04 (12)/ 2020-11-04 (43)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742167; Age (years): 34; Sex: M; Race: NOT REPORTED							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 12:15 (2)/ 2020-10-14 02:00 (13)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742175; Age (years): 43; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Injury, poisoning and procedural complications/ Injury/ TRAUMATIC INJURY	2020-10-07 (10)/ 2020-10-15 (18)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Limb injury/ TRAUMATIC INJURY LEFT HAND	2020-10-07 (10)/ 2020-10-15 (18)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742180; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ RIGORS	2020-09-29 01:00 (1)/ 2020-09-29 04:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742208; Age (years): 22; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-09-25 (24)/ 2020-09-30 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-25 (24)/ 2020-10-16 (45)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-08 (35)/ 2020-11-09 (36)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742208; Age (years): 22; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-11-08 (35)/ 2020-11-09 (36)	Yes/ No/ Yes	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752008; Age (years): 79; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-07 15:20 (1)/ 2020-08-14 (8)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752034; Age (years): 60; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-11 (2)/ 2020-09-17 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752046; Age (years): 38; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-10 (2)/ 2020-09-17 (9)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752086; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-12 (2)/ 2020-09-18 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752087; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT ARM (UNKNOWN IF URTICARIAL OR NONURTICARIAL)	2020-09-13 (3)/ 2020-09-18 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752156; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-19 (1)/ 2020-09-01 (14)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752183; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 (7)/ 2020-08-30 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752189; Age (years): 28; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE	2020-09-16 (1)/ 2020-10-01 (16)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752256; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ ACUTE NON-INTRACTABLE HEADACHE	2020-09-02 (8)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752402; Age (years): 70; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-07 (4)/ 2020-09-14 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762161; Age (years): 74; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-09 (41)/ 2020-11-15 (47)	Yes/ Yes/ No	3	Yes/2/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Sepsis/ SEPSIS	2020-11-10 (42)/ Ongoing	Yes/ Yes/ No	3	Yes/2/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-11-10 (42)/ 2020-11-11 (43)	Yes/ Yes/ No	3	Yes/2/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Pneumonia/ LEFT UPPER LOBE PNEUMONIA	2020-11-10 (42)/ 2020-11-18 (50)	Yes/ Yes/ No	3	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772069; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-15 (2)/ 2020-08-23 (10)	Yes/ No/ Yes	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-08-16 (3)/ 2020-08-23 (10)	Yes/ No/ Yes	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-08-16 (3)/ 2020-08-23 (10)	Yes/ No/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782105; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ R ARM CELLULITIS	2020-10-27 (33)/ 2020-11-04 (41)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782141; Age (years): 38; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP PHARYNGITIS	2020-10-09 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3782146; Age (years): 57; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HIGH BLOOD PRESSURE	2020-09-03 16:26 (1)/ 2020-09-03 21:45 (1)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812098; Age (years): 67; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-08-28 (19)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812132; Age (years): 72; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS ON LEFT ARM	2020-09-09 09:00 (1)/ 2020-09-17 09:00 (9)	Yes/ Yes/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822003; Age (years): 65; Sex: M; Race: WHITE							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-24 (54)/ 2020-10-27 (57)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-27)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3822043; Age (years): 75; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ B-cell small lymphocytic lymphoma/ SMALL LYMPHOCYTIC LYMPHOMA	2020-10-06 11:00 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/6	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822045; Age (years): 78; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ SEVERE KNEE PAIN	2020-08-17 (11)/ 2020-08-17 (11)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822074; Age (years): 37; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Temporomandibular joint syndrome/ TMJ EXACERBATION	2020-08-12 (2)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3832043; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Toxic shock syndrome/ SUSPECTED TOXIC SHOCK SYNDROME	2020-08-23 (22)/ 2020-08-25 (24)	Yes/ Yes/ No	3	Yes/3 (2020-08-23/ 2020-08-25)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832055; Age (years): 71; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPAL EPISODE	2020-09-20 (12)/ 2020-09-23 (15)	Yes/ Yes/ No	3	Yes/3 (2020-09-20/ 2020-09-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3852036; Age (years): 53; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-09-29 23:59 (1)/ 2020-09-30 (2)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852069; Age (years): 68; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 (24)/ 2020-09-26 (27)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-23 (24)/ 2020-09-26 (27)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852069; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-23 (24)/ 2020-10-01 (32)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862003; Age (years): 71; Sex: M; Race: WHITE							
Eye disorders/ Retinal detachment/ LEFT EYE RETINAL DETACHMENT	2020-09-04 (25)/ 2020-09-11 (32)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3862112; Age (years): 71; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-10-01 19:00 (2)/ 2020-10-22 18:00 (23)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862285; Age (years): 61; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site hypoaesthesia/ INJECTION SITE NUMBNESS	2020-10-17 (3)/ 2020-10-19 (5)	Yes/ No/ No	3	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3872018; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	2020-10-09 (39)/ 2020-10-12 (42)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3872090; Age (years): 63; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA UNSPECIFIED TYPE	2020-08-11 (5)/ 2020-09-14 (39)	Yes/ Yes/ No	3	Yes/3 (2020-08-18/ 2020-08-22)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872090; Age (years): 63; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Enteritis/ ILEITIS	2020-08-11 (5)/ 2020-09-14 (39)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Psychiatric disorders/ Insomnia/ INSOMNIA	2020-08-29 (23)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3872197; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ RIGHT HIP ABDUCTOR TENDONITIS	2020-09-08 (26)/ 2020-10-16 (64)	Yes/ Yes/ No	3	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872416; Age (years): 36; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Chest discomfort/ CHEST DISCOMFORT	2020-10-12 (41)/ 2020-10-12 (41)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912003; Age (years): 75; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-25 18:20 (1)/ 2020-08-25 18:39 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912024; Age (years): 72; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Intestinal perforation/ BOWEL PERFORATION	/ 2020-11-08 (73)	Yes/ Yes/ No	3	Yes/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Flank pain/ FLANK PAIN (LEFT)	2020-11-03 (41)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE	2020-11-12 (50)/ Ongoing	Yes/ Yes/ No	3	Yes/2/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912031; Age (years): 65; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-29 12:14 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3912033; Age (years): 62; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant melanoma in situ/ MALIGNANT MELANOMA IN SITU (R UPPER BACK)	2020-10-08 (16)/ 2020-10-08 (16)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3912048; Age (years): 66; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-31 14:31 (1)/ 2020-09-28 13:06 (28)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912056; Age (years): 70; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-31 17:45 (1)/ 2020-08-31 21:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912056; Age (years): 70; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION GRADE 3	2020-09-28 15:59 (1)/ 2020-09-28 16:06 (1)	Yes/ No/ No	3	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912114; Age (years): 74; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-04 17:06 (1)/ 2020-09-05 (2)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-30 (57)/ 2020-11-04 (62)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912116; Age (years): 58; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS-BILATERAL UPPER EXTREMITIES	2020-10-03 (2)/ Ongoing	Yes/ Yes/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912120; Age (years): 53; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION- GRADE 3	2020-10-15 (10)/ 2020-10-15 (10)	Yes/ No/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912130; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION GRADE 3	2020-09-08 16:36 (1)/ 2020-09-09 10:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912187; Age (years): 25; Sex: F; Race: WHITE							
Cardiac disorders/ Bradycardia/ WORSENING OF BRADYCARDIA	2020-09-18 14:19 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912200; Age (years): 46; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION GRADE 3	2020-09-22 15:28 (1)/ 2020-09-22 15:54 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912205; Age (years): 47; Sex: M; Race: ASIAN							
Cardiac disorders/ Bradycardia/ WORSENING OF BRADYCARDIA	2020-10-21 12:33 (1)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912224; Age (years): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-29 13:42 (1)/ 2020-10-28 09:42 (29)	Yes/ No/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932077; Age (years): 29; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ SEVERE STOMACH CRAMPING	2020-11-06 (36)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	
Gastrointestinal disorders/ Nausea/ INTERMITTENT NAUSEA	2020-11-06 (36)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	
Subject ID: US3942021; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT TRAUMA	2020-09-06 (10)/ 2020-10-01 (35)	Yes/ No/ No	3	Yes/3 (2020-09-06/ 2020-09-22)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3952055; Age (years): 58; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ GRADE 3 BLOOD PRESSURE INCREASE	2020-09-08 16:08 (1)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3952104; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Hip fracture/ HIP FRACTURE	2020-10-05 (19)/ 2020-10-08 (22)	Yes/ Yes/ No	3	Yes/3 (2020-10-07/ 2020-10-12)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3982272; Age (years): 69; Sex: F; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ NEW ONSET ATRIAL FIBRILLATION	2020-10-20 (8)/ 2020-10-27 (15)	Yes/ Yes/ No	3	Yes/3 (2020-10-20/ 2020-10-22)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3992016; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-10-01 (10)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992016; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-01 (10)/ 2020-10-09 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-01 (10)/ 2020-10-09 (18)	Yes/ Yes/ Yes	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	2020-10-02 (11)/ 2020-10-07 (16)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 (12)/ 2020-10-09 (18)	Yes/ Yes/ Yes	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.7
Unsolicited Severe TEAE
Safety Set

TEAE = Treatment-Emergent Adverse Event; MAAE = Medically-Attended Adverse Event; AR = Adverse Reaction; SAE = Serious Adverse Event; IP = Investigational Product; SP = Study Procedure.
Relative day is defined as days from the most recent injection date.
MedDRA version 23.0.
[1] Sev. = Severity, 1 = Grade 1/Mild, 2 = Grade 2/Moderate, 3 = Grade 3/Severe, 4 = Grade 4.
[2] 1 = Death, 2 = Life threatening, 3 = Requires inpatient or prolongation of existing Hospitalization (Hospital Admission Date/ Hospital Discharge Date), 4 = Persistent or significant disability or incapacity, 5 = Congenital anomaly or birth defect, 6 = Other medically important event.
[3] R = Related, NR = Not Related, NA = Not Applicable.

Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3052307; Age (years): 54; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-28 18:13 (1)/ 2020-09-02 21:48 (6)	Yes/ No/ No	3	No	R/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152020; Age (years): 43; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-07-28 18:44 (1)/ 2020-07-29 15:00 (1)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222015; Age (years): 85; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-06 15:33 (1)/ 2020-08-07 16:03 (2)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222031; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION - EXACERBATION	2020-08-07 12:51 (1)/ Ongoing	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322036; Age (years): 28; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 (6)/ 2020-10-06 (16)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362053; Age (years): 51; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ WORSENING OF MIGRAINE/HEADACHE	2020-09-05 00:00 (1)/ 2020-09-19 00:00 (15)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382155; Age (years): 41; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 (8)/ 2020-10-09 (12)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402299; Age (years): 50; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ SEVERE HEADACHE	2020-08-11 (4)/ 2020-08-16 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432023; Age (years): 83; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Polymyalgia rheumatica/ POSSIBLE POLYMYALGIA RHEUMATICA	2020-08-20 (16)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-21)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3462305; Age (years): 50; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRYALGIA IN BOTH LEGS (POST-DOSE)	2020-08-24 16:33 (1)/ 2020-09-01 13:00 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512049; Age (years): 64; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL INJECTION SITE AXILLARY LYMPHADENOPATHY	2020-09-10 07:00 (1)/ 2020-09-19 12:00 (10)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512055; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-11 (32)/ 2020-10-11 (32)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-15 (36)/ Ongoing	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 (36)/ Ongoing	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512055; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-15 (36)/ Ongoing	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 (36)/ 2020-10-15 (36)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512092; Age (years): 64; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-09-12 07:00 (1)/ 2020-09-22 07:00 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512115; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 (7)/ 2020-08-28 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-30 10:00 (2)/ Ongoing	Yes/ No/ Yes	3	No	R/ R	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-31 (3)/ 2020-09-20 (23)	Yes/ No/ Yes	3	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532272; Age (years): 33; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-10-11 (5)/ 2020-10-12 (6)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632048; Age (years): 53; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-01 13:30 (1)/ Ongoing	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682139; Age (years): 33; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-30 (14)/ 2020-10-01 (15)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Asthenia/ WEAKNESS	2020-09-30 (14)/ 2020-10-04 (18)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-30 (14)/ 2020-10-04 (18)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692088; Age (years): 56; Sex: M; Race: WHITE							
Vascular disorders/ Diastolic hypertension/ DIASTOLIC HYPERTENSION	2020-10-08 (29)/ 2020-10-16 (37)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722157; Age (years): 39; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-08 (5)/ 2020-09-08 (5)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722217; Age (years): 39; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES BILATERAL LEGS	2020-08-15 (4)/ 2020-08-22 (11)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732090; Age (years): 78; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-18 15:06 (1)/ 2020-10-05 (49)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752180; Age (years): 57; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-25 (6)/ 2020-08-30 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822158; Age (years): 26; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (2)/ 2020-09-26 (10)	Yes/ No/ Yes	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912006; Age (years): 71; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION- GRADE 3	2020-08-26 12:51 (1)/ 2020-08-26 14:05 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912026; Age (years): 72; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION (GRADE 3)	2020-09-25 11:42 (1)/ 2020-09-25 11:54 (1)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912058; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION (WORSENING OF)	2020-09-01 12:55 (1)/ 2020-09-01 13:11 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912067; Age (years): 63; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-01 16:13 (1)/ 2020-10-27 (57)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912111; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION-GRADE 3	2020-10-01 13:42 (1)/ 2020-10-01 13:52 (1)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912118; Age (years): 69; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-08 11:37 (1)/ 2020-09-08 14:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-06 12:20 (1)/ 2020-10-06 14:44 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012023; Age (years): 29; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE, LEFT ARM	2020-08-25 21:00 (1)/ 2020-09-02 (9)	Yes/ Yes/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012053; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE, LEFT ARM	2020-08-06 16:00 (1)/ 2020-08-26 (21)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022038; Age (years): 73; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-07-29 12:08 (2)/ 2020-08-05 09:00 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022038; Age (years): 73; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER	2020-07-30 (3)/ 2020-08-05 (9)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022062; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-04 (7)/ 2020-08-07 (10)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-04 (7)/ 2020-08-12 (15)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3052262; Age (years): 35; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Adverse drug reaction/ ADVERSE EFFECT OF DRUG	2020-09-18 19:00 (1)/ 2020-09-24 08:00 (6)	Yes/ Yes/ No	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122128; Age (years): 64; Sex: M; Race: WHITE							
Nervous system disorders/ Movement disorder/ DIFFICULTY RAISING LEFT ARM	2020-07-30 00:00 (1)/ 2020-08-01 23:59 (4)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212158; Age (years): 35; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY IPSILATERAL TO INJECTION SITE	2020-08-18 (6)/ 2020-08-21 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222054; Age (years): 54; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE/ARM REDNESS	2020-08-21 (14)/ 2020-08-26 (19)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222316; Age (years): 79; Sex: M; Race: WHITE							
Immune system disorders/ Type IV hypersensitivity reaction/ DELAYED TYPE-HYPERSENSITIVITY	2020-08-31 (8)/ 2020-09-04 (12)	Yes/ Yes/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312030; Age (years): 78; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS (MACULAR NON-URTICARIAL) AT INJECTION SITE (LEFT ARM)	2020-09-09 (3)/ 2020-10-18 (42)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312092; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ MACULAR NON-UTICARIAL REDNESS AT INJECTION SITE	2020-09-11 (1)/ 2020-09-21 (11)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312109; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ REDNESS AT INJECTION SITE (MACULAR/NON-UTICARIAL)	2020-09-15 (2)/ 2020-09-22 (9)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3322329; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling face/ FACIAL SWELLING	2020-10-17 (3)/ 2020-10-22 (8)	Yes/ Yes/ No	3	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362116; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ WORSENING OF CHRONIC NECK PAIN	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362116; Age (years): 56; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382134; Age (years): 33; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-30 (3)/ 2020-08-30 (3)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3382267; Age (years): 49; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ GENERALIZED RASH	2020-10-13 (2)/ Ongoing	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3432118; Age (years): 47; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC B/P	2020-09-14 (1)/ 2020-09-15 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482064; Age (years): 71; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash macular/ NON-URTICARIAL MACULAR RASH WITH BLANCHING ERYTHEMA ON LEFT DELTOID	2020-08-25 (9)/ 2020-09-04 (19)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482070; Age (years): 53; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES PAST DAY 7 OF REACTO PERIOD	2020-09-15 08:00 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3482090; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site macule/ NON-URTICARIAL, MACULAR, REDNESS ON LEFT DELTOID AT THE INJECTION SITE	2020-09-16 15:51 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482090; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-17 12:05 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3502058; Age (years): 44; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY ADENOPATHY - IPSILATERAL	2020-09-28 (4)/ Ongoing	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3512008; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INJECTION SITE INDURATION	2020-09-02 17:20 (1)/ 2020-09-13 13:01 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512008; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING	2020-09-02 17:20 (1)/ 2020-09-13 13:01 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512025; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Malaise/ MALAISE	2020-09-03 18:30 (1)/ 2020-09-17 06:00 (14)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512047; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-21 (10)/ 2020-08-27 (16)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512047; Age (years): 69; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE	2020-08-21 (10)/ 2020-08-28 (17)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512051; Age (years): 29; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-11 23:30 (2)/ 2020-09-12 07:30 (2)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512177; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LEG MUSCLE ACHES	2020-09-25 22:00 (1)/ 2020-10-09 08:30 (14)	Yes/ No/ Yes	3	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522108; Age (years): 68; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-15 (3)/ 2020-08-15 (3)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522160; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER OF 101.5	2020-09-16 14:00 (2)/ 2020-09-17 12:00 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522191; Age (years): 34; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (3)/ 2020-09-18 (3)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522664; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RIGHT DELTOID MACULAR, NON-URTICARIAL REDNESS AT INJECTION SITE 120MM BY 86MM OBLONG	2020-09-23 (13)/ 2020-09-25 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532083; Age (years): 50; Sex: F; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE	2020-09-26 08:00 (1)/ 2020-09-26 11:00 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532093; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE ERYTHEMA.	2020-09-22 (1)/ 2020-10-17 (26)	Yes/ No/ Yes	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532108; Age (years): 66; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ OPTICAL HEADACHE	2020-09-24 (2)/ 2020-09-24 (2)	Yes/ Yes/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542206; Age (years): 71; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-10 17:02 (1)/ 2020-09-22 (13)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542276; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL ELBOWS AND RIGHT KNEE ARTHRALGIAS	2020-09-23 01:00 (1)/ 2020-10-06 (15)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIAS	2020-09-23 01:00 (1)/ 2020-10-06 (15)	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3582070; Age (years): 68; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ BACK SPASMS	2020-09-25 (2)/ 2020-09-28 (5)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582114; Age (years): 40; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT (INJECTION SIDE) AXILLARY LYMPHADENOPATHY	2020-09-08 18:00 (1)/ 2020-10-06 23:59 (29)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3612004; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RETICULATE MACULAR ERYTHEMA AT INJECTION SITE, RIGHT ARM	2020-09-07 (8)/ 2020-09-11 (12)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632027; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ LEFT ARM (NON-URTICARIAL) INJECTION SITE RED PATCH	2020-09-09 (10)/ 2020-09-11 (12)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632038; Age (years): 74; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-05 11:00 (1)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632052; Age (years): 61; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-08 11:38 (1)/ 2020-10-06 (29)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3632053; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-08 11:55 (1)/ 2020-10-06 (29)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632101; Age (years): 24; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	2020-10-22 (3)/ 2020-10-23 (4)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3642250; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH FROM VACCINE #1	2020-09-26 (8)/ 2020-09-29 (11)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3642295; Age (years): 23; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-03 (1)/ Ongoing	Yes/ No/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3642312; Age (years): 46; Sex: F; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-10-14 (2)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672092; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (L)	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672093; Age (years): 24; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT SITE OF INJECTION (LEFT ARM)	2020-08-23 (11)/ 2020-08-25 (13)	Yes/ No/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3702010; Age (years): 74; Sex: M; Race: UNKNOWN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-04 (1)/ 2020-09-11 (8)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702010; Age (years): 74; Sex: M; Race: UNKNOWN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-05 20:22 (2)/ 2020-09-11 (8)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722187; Age (years): 71; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN IN THE INJECTION SITE	2020-09-10 15:00 (30)/ 2020-09-10 23:00 (31)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722224; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722224; Age (years): 52; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-19 (10)/ 2020-09-19 (10)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722239; Age (years): 20; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-10 17:00 (1)/ 2020-09-11 22:00 (2)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742167; Age (years): 34; Sex: M; Race: NOT REPORTED							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 12:15 (2)/ 2020-10-14 02:00 (13)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742180; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ RIGORS	2020-09-29 01:00 (1)/ 2020-09-29 04:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752034; Age (years): 60; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-11 (2)/ 2020-09-17 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752046; Age (years): 38; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-10 (2)/ 2020-09-17 (9)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752086; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-12 (2)/ 2020-09-18 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752087; Age (years): 44; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE LEFT ARM (UNKNOWN IF URTICARIAL OR NONURTICARIAL)	2020-09-13 (3)/ 2020-09-18 (8)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752156; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-19 (1)/ 2020-09-01 (14)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752183; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 (7)/ 2020-08-30 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752189; Age (years): 28; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AT INJECTION SITE	2020-09-16 (1)/ 2020-10-01 (16)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752402; Age (years): 70; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-07 (4)/ 2020-09-14 (11)	Yes/ No/ Yes	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772069; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-15 (2)/ 2020-08-23 (10)	Yes/ No/ Yes	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES IN SEVERAL JOINTS	2020-08-16 (3)/ 2020-08-23 (10)	Yes/ No/ Yes	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772069; Age (years): 58; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-08-16 (3)/ 2020-08-23 (10)	Yes/ No/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812132; Age (years): 72; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS ON LEFT ARM	2020-09-09 09:00 (1)/ 2020-09-17 09:00 (9)	Yes/ Yes/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822043; Age (years): 75; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ B-cell small lymphocytic lymphoma/ SMALL LYMPHOCYTIC LYMPHOMA	2020-10-06 11:00 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/6	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822074; Age (years): 37; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Temporomandibular joint syndrome/ TMJ EXACERBATION	2020-08-12 (2)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3852036; Age (years): 53; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-09-29 23:59 (1)/ 2020-09-30 (2)	Yes/ No/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912003; Age (years): 75; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-25 18:20 (1)/ 2020-08-25 18:39 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912056; Age (years): 70; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-31 17:45 (1)/ 2020-08-31 21:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912116; Age (years): 58; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS-BILATERAL UPPER EXTREMITIES	2020-10-03 (2)/ Ongoing	Yes/ Yes/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912130; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION GRADE 3	2020-09-08 16:36 (1)/ 2020-09-09 10:00 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912200; Age (years): 46; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION GRADE 3	2020-09-22 15:28 (1)/ 2020-09-22 15:54 (1)	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952055; Age (years): 58; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ GRADE 3 BLOOD PRESSURE INCREASE	2020-09-08 16:08 (1)/ Ongoing	Yes/ No/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.8
Unsolicited Treatment-Related Severe TEAE
Safety Set

TEAE = Treatment-Emergent Adverse Event; MAAE = Medically-Attended Adverse Event; AR = Adverse Reaction; SAE = Serious Adverse Event; IP = Investigational Product; SP = Study Procedure.
Relative day is defined as days from the most recent injection date.
MedDRA version 23.0.
[1] Sev. = Severity, 1 = Grade 1/Mild, 2 = Grade 2/Moderate, 3 = Grade 3/Severe, 4 = Grade 4.
[2] 1 = Death, 2 = Life threatening, 3 = Requires inpatient or prolongation of existing Hospitalization (Hospital Admission Date/ Hospital Discharge Date), 4 = Persistent or significant disability or incapacity, 5 = Congenital anomaly or birth defect, 6 = Other medically important event.
[3] R = Related, NR = Not Related, NA = Not Applicable.

Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002031; Age (years): 25; Sex: F; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]: SO							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-09 (44)/ 2020-09-12 (47)	Yes/ Yes/ No	2	Yes/3 (2020-09-09/ 2020-09-12)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3002046; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Hip fracture/ LEFT BROKEN HIP	2020-08-12 (15)/ 2020-08-14 (17)	Yes/ Yes/ No	3	Yes/3 (2020-08-12/)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012263; Age (years): 50; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Injury, poisoning and procedural complications/ Gun shot wound/ GUNSHOT WOUND, RIGHT SHOULDER AND SPINE	2020-11-08 (40)/ Ongoing	Yes/ Yes/ No	4	Yes/2/3 (2020-11-09/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pneumothorax/ BILATERAL LUNG COLLAPSE	2020-11-09 (41)/ 2020-11-15 (47)	Yes/ Yes/ No	4	Yes/2/3 (2020-11-08/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022186; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Rib fracture/ FRACTURE RIBS	2020-10-11 (18)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-11/ 2020-10-14)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022186; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Syncope/ SYNCOPE	2020-10-11 (18)/ 2020-10-11 (18)	Yes/ Yes/ No	4	Yes/3 (2020-10-11/ 2020-10-14)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-11 (18)/ 2020-10-14 (21)	Yes/ Yes/ No	4	Yes/3 (2020-10-11/ 2020-10-14)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-11 (49)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022186; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-11-11 (49)/ 2020-11-13 (51)	Yes/ Yes/ No	4	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022291; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL/SO							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF RIGHT KNEE ARTHRITIS	2020-11-09 (43)/ 2020-11-12 (46)	Yes/ Yes/ No	4	Yes/3 (2020-11-09/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3032204; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (57)/ 2020-11-16 (64)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	FATAL

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032277; Age (years): 90; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Gastrointestinal disorders/ Duodenal ulcer haemorrhage/ ACUTE DUODENAL ULCER WITH HEMORRHAGE	2020-09-12 (24)/ 2020-09-17 (29)	Yes/ Yes/ No	4	Yes/3 (2020-09-13/ 2020-09-17)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3042264; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ 3 RUPTURED DISCS IN LUMBAR SPINE	2020-10-26 (40)/ Ongoing	Yes/ Yes/ No	1	Yes/3 (2020-10-26/ 2020-10-28)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3052295; Age (years): 38; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Syncope/ SYNCOPE	2020-09-24 14:08 (2)/ 2020-09-25 10:18 (2)	Yes/ Yes/ No	3	Yes/3 (2020-09-24/ 2020-09-26)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3062167; Age (years): 56; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-10-16 (39)/ Ongoing	Yes/ Yes/ No	4	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082269; Age (years): 75; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Gastric perforation/ INTRA-ABDOMINAL PERFORATION	2020-10-02 (12)/ 2020-10-03 (13)	Yes/ Yes/ No	4	Yes/1/3 (2020-10-02/)/4/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	FATAL
Subject ID: US3092043; Age (years): 69; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL							
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA EXACERBATION	2020-10-02 (30)/ 2020-11-10 (69)	Yes/ Yes/ No	2	Yes/3 (2020-10-28/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092043; Age (years): 69; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION	2020-10-02 (30)/ 2020-11-10 (69)	Yes/ Yes/ No	2	Yes/3 (2020-10-28/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3092245; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO							
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT	2020-11-21 (54)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-21/)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102283; Age (years): 57; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (48)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-14/ 2020-11-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112164; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Coronary artery disease/ SEVERE CORONARY ARTERY DISEASE	2020-09-18 (11)/ 2020-09-24 (17)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-18/ 2020-09-24)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112164; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	2020-10-02 (25)/ 2020-10-02 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-02/ 2020-10-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3112192; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Atrial fibrillation/ PAROXYSMAL ATRIAL FIBRILLATION	2020-10-17 (37)/ 2020-10-20 (40)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112223; Age (years): 65; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Infections and infestations/ Pharyngitis streptococcal/ STREP-PHARYNGITIS	2020-09-01 (20)/ 2020-09-14 (33)	Yes/ Yes/ No	3	Yes/3 (2020-09-02/ 2020-09-03)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112365; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Thoracic vertebral fracture/ T12 FRACTURE	2020-10-28 (38)/ 2020-11-02 (43)	Yes/ Yes/ No	4	Yes/3 (2020-11-02/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152194; Age (years): 54; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ BILATERAL PULMONARY EMBOLISM WITH PULMONARY INFARCTS	2020-09-21 (11)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162006; Age (years): 75; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Renal and urinary disorders/ Acute kidney injury/ ACUTE RENAL FAILURE	2020-11-11 (80)/ 2020-11-12 (81)	Yes/ Yes/ No	4	Yes/3 (2020-11-11/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172038; Age (years): 34; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Septic shock/ SEPTIC SHOCK	2020-09-01 (22)/ 2020-09-03 (24)	Yes/ No/ No	4	Yes/2/3 (2020-09-01/ 2020-09-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Metabolic acidosis/ PROFOUND METABOLIC ACIDOSIS	2020-09-01 (22)/ 2020-09-03 (24)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-01/ 2020-09-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172038; Age (years): 34; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE HYPOXEMIC RESPIRATOY FAILURE	2020-09-01 (22)/ 2020-09-03 (24)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-01/ 2020-09-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Pyelonephritis acute/ ACUTE PYELONEPHRITIS (RIGHT KIDNEY)	2020-09-01 (22)/ 2020-09-26 (47)	Yes/ No/ No	4	Yes/2/3 (2020-09-01/ 2020-09-04)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172069; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-09-04 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172185; Age (years): 61; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Cardiac disorders/ Acute left ventricular failure/ ACUTE EXACERBATION OF SYSTOLIC HEART FAILURE	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172185; Age (years): 61; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILATION WITH RAPID VENTRICULAR RATE	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172205; Age (years): 55; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-10-14 (29)/ 2020-10-25 (40)	Yes/ No/ No	3	Yes/3 (2020-10-14/ 2020-10-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172250; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
Cardiac disorders/ Cardiac failure congestive/ ACUTE EXACERBATION OF CONGESTION HEART FAILURE	2020-09-12 (24)/ 2020-09-16 (28)	Yes/ Yes/ No	3	Yes/3 (2020-09-12/ 2020-09-16)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172322; Age (years): 51; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ WORSENING OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE	2020-10-10 (17)/ 2020-11-12 (50)	Yes/ Yes/ No	3	Yes/3 (2020-10-10/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172349; Age (years): 35; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Pregnancy, puerperium and perinatal conditions/ Abortion spontaneous/ MISCARRIAGE	2020-10-06 (42)/ 2020-10-13 (49)	Yes/ Yes/ No	2	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3182227; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-10-06 (29)/ 2020-10-09 (32)	Yes/ Yes/ No	4	Yes/3 (2020-10-06/ 2020-10-09)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Syncope/ SYNCOPE	2020-10-24 (47)/ 2020-10-26 (49)	Yes/ Yes/ No	4	Yes/3 (2020-10-24/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192291; Age (years): 70; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Clostridium difficile colitis/ C-DIFF - COLITIIS	2020-11-02 (52)/ 2020-11-10 (60)	Yes/ Yes/ No	4	Yes/3 (2020-11-02/ 2020-11-10)	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192614; Age (years): 60; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Cardiac disorders/ Pericarditis/ PERICARDITIS	2020-09-11 (12)/ 2020-09-15 (16)	Yes/ Yes/ No	2	Yes/3 (2020-09-14/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222059; Age (years): 84; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Atrial fibrillation/ NEW ONSET-ATRIAL FIBRILLATION	2020-09-03 (27)/ 2020-09-05 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-05)/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222068; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-24 (16)/ 2020-10-05 (27)	Yes/ Yes/ No	4	Yes/3 (2020-09-24/ 2020-10-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222189; Age (years): 57; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
General disorders and administration site conditions/ Precancerous condition/ PRE-CANCEROUS ULCER OF STOMACH AND ESOPHAGUS	2020-09-21 (4)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-21/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Psychiatric disorders/ Alcohol abuse/ ALCOHOL ABUSE	2020-10-10 (23)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-10/)/6	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222311; Age (years): 68; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-28 (6)/ 2020-09-30 (8)	Yes/ Yes/ No	4	Yes/3 (2020-09-28/ 2020-09-30)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222315; Age (years): 72; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Surgical and medical procedures/ Hip arthroplasty/ ARTHROPLASTY - RIGHT HIP	2020-09-09 (17)/ 2020-11-09 (78)	Yes/ Yes/ No	4	Yes/3 (2020-09-09/ 2020-09-10)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222367; Age (years): 39; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-11-23 (57)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-23/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222430; Age (years): 60; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: H							
Surgical and medical procedures/ Jaw operation/ JAW SURGERY	2020-11-05 (36)/ 2020-11-06 (37)	Yes/ Yes/ No	3	Yes/3 (2020-11-05/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3222611; Age (years): 55; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Nervous system disorders/ Basal ganglia haemorrhage/ LEFT BASAL GANGLIA HEMORRHAGE	2020-10-29 (15)/ 2020-11-10 (27)	Yes/ Yes/ No	4	Yes/3 (2020-10-29/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242051; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Ankle fracture/ TRIMALLEOLAR ANKLE FRACTURE, RIGHT	2020-11-01 (52)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-02/ 2020-11-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3242264; Age (years): 49; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Skin laceration/ HEAD LACERATION	2020-11-20 (54)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-20/ 2020-11-22)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252119; Age (years): 57; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-14 (37)/ 2020-10-20 (43)	Yes/ Yes/ No	4	Yes/2/3 (2020-10-14/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3252553; Age (years): 74; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Injury, poisoning and procedural complications/ Ankle fracture/ RIGHT ANKLE FRACTURE	2020-10-23 00:00 (29)/ Ongoing	Yes/ Yes/ No	2	Yes/3	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252602; Age (years): 52; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-11-06 (8)/ 2020-11-06 (8)	Yes/ Yes/ No	3	Yes/3 (2020-11-06/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272026; Age (years): 46; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ COVID-19/ COVID19	2020-11-08 (62)/ Ongoing	Yes/ Yes/ No	4	Yes/2/3 (2020-11-16/)/4	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3272031; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SO/D							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Breast cancer stage I/ STAGE 1 LEFT BREAST CANCER	2020-08-17 (17)/ 2020-08-27 (27)	Yes/ Yes/ No	2	Yes/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272035; Age (years): 61; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING RIGHT KNEE PAIN	2020-02-03 (-182)/ 2020-09-22 (51)	No/ Yes/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3272070; Age (years): 74; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-01 (29)/ 2020-10-01 (29)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ NONE	FATAL

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272085; Age (years): 58; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ WORSENING INTERMITTENT CHEST WALL PAIN NON CARDIAC	2020-10-07 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-09/ 2020-10-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272144; Age (years): 29; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
Infections and infestations/ COVID-19/ COVID 19 ILLNESS	2020-11-02 (53)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-12/ 2020-11-19)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272195; Age (years): 44; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ COVID-19/ COVID-19	2020-10-30 (44)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-07/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ COVID-19 pneumonia/ PNEUMONIA SECONDARY TO COVID 19 POSITIVE INFECTION	2020-11-07 (52)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-07/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272195; Age (years): 44; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Hypoxia/ HYPOXIA	2020-11-07 (52)/ 2020-11-12 (57)	Yes/ Yes/ No	3	Yes/3 (2020-11-07/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292236; Age (years): 80; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Vascular disorders/ Fibromuscular dysplasia/ FIBROMUSCULAR DYSPLASIA	2020-09-04 (16)/ 2020-09-05 (17)	Yes/ Yes/ No	2	Yes/3 (2020-09-04/ 2020-09-05)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292320; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Cartilage injury/ LEFT HIP LABRUM TEAR	2020-08-27 (3)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-30/ 2020-09-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292339; Age (years): 70; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Skin and subcutaneous tissue disorders/ Angioedema/ ANGIOEDEMA	2020-09-16 (21)/ 2020-09-18 (23)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-17/ 2020-09-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3302383; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE RESPIRATORY FAILURE	2020-09-26 (32)/ 2020-09-28 (34)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-28)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312187; Age (years): 31; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Musculoskeletal and connective tissue disorders/ Rhabdomyolysis/ RHABDOMYOLISIS	2020-11-08 (53)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-12/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3312212; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Osteomyelitis/ LEFT GREAT TOE OSTEOMYELITIS	2020-09-04 (15)/ 2020-10-16 (57)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-09)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: RECOVERED WITH SEQUALAE LEFT GREAT TOE AMPUTATION

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312605; Age (years): 24; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-19 (12)/ 2020-11-02 (26)	Yes/ Yes/ No	3	Yes/3 (2020-10-27/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312629; Age (years): 53; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2020-11-06 (25)/ 2020-11-10 (29)	Yes/ Yes/ No	3	Yes/3 (2020-11-06/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322013; Age (years): 61; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Syncope/ CONVULSIVE SYNCOPE	2020-09-14 (29)/ 2020-09-14 (29)	Yes/ No/ No	3	Yes/6	NR/ R	DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3322199; Age (years): 64; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Myocardial infarction/ FATAL MYOCARDIAL INFARCTION	2020-11-16 (47)/ 2020-11-16 (47)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ NONE	FATAL

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342088; Age (years): 50; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Colon cancer stage III/ STAGE III COLON CANCER	2020-09-15 (30)/ Ongoing	Yes/ Yes/ No	2	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342199; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Colitis/ ACUTE FOCAL COLITIS	2020-09-13 (10)/ 2020-09-25 (22)	Yes/ Yes/ No	3	Yes/3 (2020-09-13/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342200; Age (years): 44; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Intraductal proliferative breast lesion/ DUCTAL CARCINOMA IN SITU RIGHT BREAST	2020-11-20 (52)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342256; Age (years): 43; Sex: M; Race: UNKNOWN; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Cardio-respiratory arrest/ CARDIOPULMONARY ARREST	2020-09-20 (7)/ 2020-09-20 (7)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	FATAL

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352033; Age (years): 61; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Acute myocardial infarction/ ACUTE INFERIOR WALL MYOCARDIAL INFARCTION	2020-11-05 (57)/ 2020-11-05 (57)	Yes/ Yes/ No	4	Yes/3 (2020-11-05/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352424; Age (years): 53; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-10-05 (12)/ 2020-10-18 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-05 (12)/ 2020-10-18 (25)	Yes/ Yes/ No	3	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3352424; Age (years): 53; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-05 (12)/ 2020-10-18 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	2020-10-17 (24)/ 2020-10-18 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	2020-10-17 (24)/ 2020-10-18 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3372005; Age (years): 94; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Hip fracture/ FRACTURED LEFT HIP	2020-08-25 (22)/ 2020-08-26 (23)	Yes/ No/ No	3	Yes/3 (2020-08-25/ 2020-08-31)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3372060; Age (years): 60; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Injury, poisoning and procedural complications/ Joint injury/ RIGHT HIP TRAUMA	2020-08-14 (8)/ 2020-08-16 (10)	Yes/ No/ No	2	Yes/3 (2020-08-14/ 2020-08-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Joint injury/ RIGHT KNEE TRAUMA	2020-08-14 (8)/ 2020-09-04 (29)	Yes/ No/ No	2	Yes/3 (2020-08-14/ 2020-08-16)	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372184; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-09-02 (15)/ 2020-09-02 (15)	Yes/ No/ No	3	Yes/3 (2020-09-02/ 2020-09-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3392251; Age (years): 65; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-10-20 (13)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-20/)	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402029; Age (years): 34; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
Infections and infestations/ COVID-19/ COVID-19	2020-09-29 (37)/ 2020-10-12 (50)	Yes/ Yes/ No	4	Yes/3 (2020-10-07/ 2020-10-13)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402194; Age (years): 57; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Infections and infestations/ COVID-19/ COVID-19	2020-11-05 (65)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-16/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402299; Age (years): 50; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Post procedural haemorrhage/ POST OPERATIVE BLEEDING	2020-08-26 (19)/ 2020-09-01 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-26/ 2020-09-01)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402381; Age (years): 67; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-09-20 (7)/ Ongoing	Yes/ Yes/ No	2	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402382; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-08-28 (13)/ 2020-09-01 (17)	Yes/ Yes/ No	3	Yes/3 (2020-08-28/ 2020-09-01)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402425; Age (years): 36; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2020-11-17 (54)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-17/)	NA/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402448; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Respiratory, thoracic and mediastinal disorders/ Emphysema/ WORSENING OF EMPHYSEMA	2020-11-09 (20)/ 2020-11-11 (22)	Yes/ Yes/ No	3	Yes/3 (2020-11-09/ 2020-11-11)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT WAS SENT HOME ON 2 LITERS OF CONTINUOUS OXYGEN

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412081; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-11-13 (75)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-13/)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3412184; Age (years): 73; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Intraductal proliferative breast lesion/ RIGHT BREAST DUCTAL CARCINOMA IN SITU	2020-08-12 (3)/ Ongoing	Yes/ No/ No	2	Yes/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412328; Age (years): 64; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
General disorders and administration site conditions/ Chest pain/ ATYPICAL CHEST PAIN	2020-09-17 (23)/ 2020-09-18 (24)	Yes/ Yes/ No	4	Yes/3 (2020-09-17/ 2020-09-18)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422281; Age (years): 65; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS	2020-10-27 (14)/ 2020-10-28 (15)	Yes/ Yes/ No	3	Yes/3 (2020-10-27/ 2020-10-28)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432023; Age (years): 83; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Musculoskeletal and connective tissue disorders/ Polymyalgia rheumatica/ POSSIBLE POLYMYALGIA RHEUMATICA	2020-08-20 (16)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-21)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3432202; Age (years): 77; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Vascular disorders/ Hypertensive urgency/ HYPERTENSIVE URGENCY	2020-09-25 (10)/ 2020-09-30 (15)	Yes/ Yes/ No	3	Yes/3 (2020-09-25/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432208; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ SPINAL STENOSIS	2020-09-07 (19)/ 2020-10-05 (47)	Yes/ Yes/ No	3	Yes/3 (2020-10-02/ 2020-10-05)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432260; Age (years): 45; Sex: F; Race: OTHER: (b) (6) Risk Factors for Severe COVID-19[4]:							
Surgical and medical procedures/ Spinal fusion surgery/ CERVICAL FUSION C5-C6	2020-11-04 (45)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-04/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432295; Age (years): 83; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Skin and subcutaneous tissue disorders/ Dermatitis bullous/ DIFFUSE BULLOUS RASH (NON-URTICARIAL)	2020-09-12 (18)/ 2020-10-02 (38)	Yes/ Yes/ No	4	Yes/1/3 (2020-09-17/ 2020-09-24)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	FATAL
General disorders and administration site conditions/ Systemic inflammatory response syndrome/ SEVERE SYSTEMIC INFLAMMATORY SYNDROME IN THE SETTING OF CLL	2020-10-01 (37)/ 2020-10-02 (38)	Yes/ Yes/ No	4	Yes/1/3 (2020-10-01/ 2020-10-02)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	FATAL

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462111; Age (years): 57; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Respiratory, thoracic and mediastinal disorders/ Laryngeal oedema/ LARYNGEAL EDEMA	2020-09-19 (5)/ 2020-09-24 (10)	Yes/ Yes/ No	4	Yes/3 (2020-09-19/ 2020-09-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462116; Age (years): 43; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE	2020-09-03 08:00 (23)/ 2020-09-09 17:00 (30)	Yes/ Yes/ No	4	Yes/3 (2020-09-05/ 2020-09-09)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462255; Age (years): 57; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2020-10-16 08:00 (30)/ 2020-10-17 12:00 (31)	Yes/ Yes/ No	4	Yes/3 (2020-10-16/ 2020-10-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-16 08:00 (30)/ 2020-10-17 12:00 (31)	Yes/ Yes/ No	4	Yes/3 (2020-10-16/ 2020-10-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462388; Age (years): 46; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pneumonia aspiration/ ASPIRATION PNEUMONIA	2020-09-25 (26)/ 2020-10-04 (35)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482145; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC							
Cardiac disorders/ Cardiac failure acute/ ACUTE CARDIAC HEART FAILURE EXACERBATION	2020-09-02 (8)/ 2020-09-13 (19)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-02/ 2020-09-13)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Streptococcal sepsis/ SEPSIS RELATED TO STREPTOCOCCUS BACTEREMIA	2020-09-02 (8)/ 2020-09-13 (19)	Yes/ Yes/ No	4	Yes/3 (2020-09-02/ 2020-09-13)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Gout/ GOUT EXACERBATION IN RIGHT KNEE	2020-09-26 (32)/ 2020-09-30 (36)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482145; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC							
Renal and urinary disorders/ Chronic kidney disease/ ACUTE EXACERBATION OF CHRONIC KIDNEY DISEASE STAGE III	2020-09-26 (32)/ 2020-09-30 (36)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Anaemia/ EXACERBATION OF ANEMIA	2020-10-22 (58)/ 2020-10-26 (62)	Yes/ Yes/ No	3	Yes/3 (2020-10-22/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482145; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC							
Cardiac disorders/ Cardiac failure acute/ ACUTE DECOMPENSATED HEART FAILURE	2020-11-09 (76)/ 2020-11-10 (77)	Yes/ Yes/ No	4	Yes/3 (2020-11-09/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492064; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: D							
Nervous system disorders/ Cerebrovascular accident/ CEREBROVASCULAR ACCIDENT	2020-10-31 (30)/ 2020-11-11 (41)	Yes/ Yes/ No	3	Yes/3 (2020-10-31/ 2020-11-11)/4	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: RIGHT LOWER EXTREMITY WEAKNESS
Subject ID: US3502045; Age (years): 55; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Nervous system disorders/ Migraine/ MIGRAINE EXACERBATION	2020-09-16 (20)/ 2020-09-23 (27)	Yes/ Yes/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502142; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Multiple sclerosis/ MULTIPLE SCLEROSIS	2020-11-12 (38)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-12/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522077; Age (years): 62; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISMS (RIGHT MAIN PULMONARY ARTERY, LEFTS LOWER LOBAR BRANCH)	2020-10-15 (36)/ 2020-10-19 (40)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-19)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3522128; Age (years): 70; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC/D							
Cardiac disorders/ Atrial flutter/ ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE	2020-09-25 (15)/ 2020-09-27 (17)	Yes/ Yes/ No	4	Yes/3 (2020-09-25/ 2020-09-27)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Pneumonia/ MULTIFOCAL PNEUMONIA IN BOTH LUNGS	2020-10-08 (28)/ 2020-10-12 (32)	Yes/ Yes/ No	4	Yes/3 (2020-10-08/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522269; Age (years): 44; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-07 (18)/ 2020-09-15 (26)	Yes/ Yes/ No	4	Yes/3 (2020-09-12/ 2020-09-16)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3522269; Age (years): 44; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-08 (19)/ 2020-09-15 (26)	Yes/ Yes/ No	4	Yes/3 (2020-09-12/ 2020-09-16)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-08 (19)/ 2020-09-15 (26)	Yes/ Yes/ No	4	Yes/3 (2020-09-12/ 2020-09-16)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532063; Age (years): 70; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Femur fracture/ FRACTURED FEMUR	2020-10-28 (43)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-28/ 2020-11-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Subject ID: US3532158; Age (years): 75; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Penile cancer/ CANCEROUS TUMOR-PENIS	2020-11-16 (55)/ Ongoing	Yes/ Yes/ No	3	Yes/2	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3532170; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Cardiac disorders/ Acute myocardial infarction/ ACUTE MYOCARDIAL INFARTION	2020-09-06 (11)/ 2020-10-06 (41)	Yes/ Yes/ No	4	Yes/3 (2020-09-06/ 2020-10-06)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3542168; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Anxiety/ ANXIETY EXACERBATION	2020-09-10 (7)/ 2020-09-18 (15)	Yes/ Yes/ No	4	Yes/3 (2020-09-10/ 2020-09-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Anxiety/ ANXIETY EXACERBATION	2020-09-19 (16)/ 2020-09-23 (20)	Yes/ Yes/ No	3	Yes/3 (2020-09-19/ 2020-09-23)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Depression/ DEPRESSION EXACERBATION	2020-09-19 (16)/ 2020-09-23 (20)	Yes/ Yes/ No	3	Yes/3 (2020-09-19/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552140; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO							
Eye disorders/ Retinal detachment/ RETINAL DETACHMENT OF LEFT EYE	2020-09-08 (18)/ 2020-09-12 (22)	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Eye disorders/ Retinal tear/ HORSESHOE TEAR OF RIGHT EYE	2020-10-01 (41)/ 2020-10-06 (46)	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Cardiac disorders/ Acute myocardial infarction/ NON-ST ELEVATED MYOCARDIAL INFARCTION	2020-09-26 (29)/ 2020-09-26 (29)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hypomagnesaemia/ HYPOMAGNESIA	2020-09-26 (29)/ 2020-10-08 (41)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-09-26 (29)/ 2020-10-08 (41)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Cardiac disorders/ Atrial fibrillation/ PAROXYSMAL ATRIAL FIBRILLATION	2020-09-26 (29)/ 2020-10-30 (63)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: 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.

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Respiratory, thoracic and mediastinal disorders/ Organising pneumonia/ CRYPTOGENIC ORGANIZING PNEUMONIA	2020-09-26 (29)/ 2020-11-19 (83)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE	2020-09-28 (31)/ 2020-11-19 (83)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552331; Age (years): 44; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-09-15 (12)/ 2020-10-01 (28)	Yes/ Yes/ No	4	Yes/3 (2020-09-16/ 2020-09-21)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572134; Age (years): 48; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-11-09 (42)/ 2020-11-13 (46)	Yes/ Yes/ No	3	Yes/3 (2020-11-09/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3572167; Age (years): 43; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Vascular disorders/ Accelerated hypertension/ ACELERATED HYPERTENSION	2020-10-27 (27)/ 2020-10-30 (30)	Yes/ No/ No	3	Yes/3 (2020-10-27/ 2020-10-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN; Risk Factors for Severe COVID-19[4]:							
General disorders and administration site conditions/ Swelling face/ SWELLING TO THE RIGHT SIDE OF THE FACE	2020-09-17 (7)/ 2020-09-27 (17)	Yes/ Yes/ No	2	Yes/6	R/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ TINGLING ON RIGHT SIDE OF FACE	2020-09-17 (7)/ 2020-09-28 (18)	Yes/ Yes/ No	2	Yes/6	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Immunisation anxiety related reaction/ ANXIETY RELATED TO THE VACCINE	2020-09-17 (7)/ 2020-10-07 (27)	Yes/ Yes/ No	2	Yes/6	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ LEFT SIDED PLEURITIC CHEST PAIN	2020-09-27 (17)/ 2020-09-29 (19)	Yes/ Yes/ No	1	Yes/6	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN; Risk Factors for Severe COVID-19[4]:							
General disorders and administration site conditions/ Feeling hot/ LEFT SIDED CHEST WALL WARMTH	2020-10-06 (26)/ 2020-10-16 (36)	Yes/ Yes/ No	2	Yes/4	R/ R	DOSE DELAYED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ LEFT SIDED TINGLING	2020-10-06 (26)/ 2020-10-16 (36)	Yes/ Yes/ No	2	Yes/4/6	R/ R	DOSE DELAYED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602051; Age (years): 52; Sex: M; Race: OTHER: OTHER RACE; Risk Factors for Severe COVID-19[4]: CL							
Vascular disorders/ Aortic stenosis/ WORSENING OF AORTIC STENOSIS	2020-10-28 (15)/ 2020-11-02 (20)	Yes/ Yes/ No	4	Yes/3 (2020-10-29/ 2020-11-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: PT WITH OPEN SURGERY AND POST OP RECOVERY ONGOING
Injury, poisoning and procedural complications/ Procedural haemorrhage/ INCREASED BLEEDING INTRA OPERATIVE TIME	2020-10-29 (16)/ 2020-10-29 (16)	Yes/ Yes/ No	4	Yes/4	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3612010; Age (years): 67; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Vascular disorders/ Aortic aneurysm/ ABDOMINAL AORTIC ANEURYSM (3CM)	2020-10-16 (17)/ Ongoing	Yes/ Yes/ No	1	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622282; Age (years): 51; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/H							
Surgical and medical procedures/ Foot operation/ FOOT/ANKLE SURGERY	2020-11-05 (16)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-05/)	NR/ NR	DOSE NOT CHANGED/	UNKNOWN

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632022; Age (years): 68; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Leiomyosarcoma metastatic/ METASTATIC LEIOMYOSARCOMA	2020-11-20 (57)/ Ongoing	Yes/ Yes/ No	4	Yes/2	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632032; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO							
Vascular disorders/ Hypertensive emergency/ HYPERTENSIVE EMERGENCY	2020-09-16 14:15 (1)/ 2020-09-18 16:27 (3)	Yes/ Yes/ No	4	Yes/2	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632127; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO							
Social circumstances/ Sexual abuse/ SEXUAL ASSAULT	2020-11-07 (26)/ 2020-11-07 (26)	Yes/ Yes/ No	4	Yes/2/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662033; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Appendicitis/ ACUTE APPENDICITIS	2020-09-08 (8)/ 2020-09-09 (9)	Yes/ Yes/ No	3	Yes/3 (2020-09-08/ 2020-09-10)/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662033; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-08 (8)/ 2020-09-10 (10)	Yes/ Yes/ No	3	Yes/3 (2020-09-08/ 2020-09-10)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3662181; Age (years): 61; Sex: M; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Psychotic disorder/ PSYCHOSIS, UNSPECIFIED	2020-10-26 (5)/ 2020-10-30 (9)	Yes/ Yes/ No	3	Yes/3 (2020-10-26/ 2020-10-30)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672199; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D							
Injury, poisoning and procedural complications/ Post procedural haematoma/ HEMATOMA R GROIN FOLLOWING ANGIOPLASTY	2020-10-06 (19)/ 2020-10-08 (21)	Yes/ Yes/ No	3	Yes/3 (2020-10-06/ 2020-10-08)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672232; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ COVID-19/ COVID-19	2020-11-11 (55)/ Ongoing	Yes/ No/ Yes	2	Yes/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3672243; Age (years): 46; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ COVID-19/ COVID-19	2020-11-12 (50)/ Ongoing	Yes/ No/ Yes	2	Yes/6	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672278; Age (years): 78; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D							
Nervous system disorders/ Speech disorder/ SPEECH DEFICIT	2020-09-10 (11)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-09-10/ 2020-09-11)/4	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Nervous system disorders/ Ischaemic stroke/ ISCHEMIC STROKE (FRONTAL LOBE)	2020-09-10 (11)/ 2020-09-11 (12)	Yes/ Yes/ No	4	Yes/3 (2020-09-10/ 2020-09-11)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: AE OF SPEECH DEFICIT
Subject ID: US3692016; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Vascular disorders/ Peripheral artery aneurysm/ ILIAC ARTERY ANEURYSM	2020-11-01 (40)/ 2020-11-02 (41)	Yes/ Yes/ No	2	Yes/3 (2020-11-01/ 2020-11-08)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722034; Age (years): 65; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer metastatic/ METASTATIC CASTRATE SENSITIVE PROSTRATE CANCER WITH METASTASES	2020-09-23 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3722066; Age (years): 67; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Infections and infestations/ COVID-19/ POSITIVE COVID 19	2020-11-11 (76)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-16/)	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722338; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Gastrointestinal disorders/ Umbilical hernia/ UMBILICAL HERNIA	2020-10-13 (27)/ 2020-10-21 (35)	Yes/ Yes/ No	3	Yes/3 (2020-10-13/ 2020-10-21)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732110; Age (years): 81; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Product issues/ Lead dislodgement/ DISPLACED AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD	2020-10-08 (22)/ 2020-10-08 (22)	Yes/ Yes/ No	2	Yes/3 (2020-10-08/ 2020-10-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732304; Age (years): 55; Sex: F; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ BILATERAL PULMONARY EMBOLISM	2020-10-29 (23)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-29/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742342; Age (years): 18; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Major depression/ MAJOR DEPRESSIVE DISORDER WITHOUT PSYCHOTIC FEATURES	2020-09-16 (6)/ 2020-09-17 (7)	Yes/ Yes/ No	3	Yes/3 (2020-09-16/ 2020-09-17)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742384; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-11-01 (20)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-01/ 2020-11-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752025; Age (years): 58; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Infections and infestations/ COVID-19/ COVID-19	2020-11-08 (49)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-10/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Hypotension/ HYPOTENSION REQUIRING HOSPITALIZATION	2020-11-10 (51)/ 2020-11-13 (54)	Yes/ Yes/ No	4	Yes/3 (2020-11-10/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772051; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
General disorders and administration site conditions/ Incarcerated hernia/ ACUTE INCARCERATED VENTRAL HERNIA	2020-09-04 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-05/ 2020-09-14)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3792094; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SO/D							
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-10-20 (12)/ 2020-10-22 (14)	Yes/ No/ No	4	Yes/3 (2020-10-20/ 2020-10-22)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3802046; Age (years): 70; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-13 (52)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-21/ 2020-11-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812059; Age (years): 20; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Anxiety disorder/ ANXIETY DISORDER	2020-10-24 (54)/ 2020-11-10 (71)	Yes/ Yes/ No	4	Yes/3 (2020-10-26/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Major depression/ SEVERE EPISODE OF RECURRENT MAJOR DEPRESSIVE DISORDER	2020-10-29 (59)/ 2020-11-10 (71)	Yes/ Yes/ No	4	Yes/3 (2020-10-29/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Major depression/ SEVERE EPISODE OF RECURRENT MAJOR DEPRESSIVE DISORDER	2020-11-18 (79)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-18/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812280; Age (years): 29; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-11-12 (50)/ 2020-11-17 (55)	Yes/ Yes/ No	4	Yes/3 (2020-11-13/ 2020-11-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822015; Age (years): 83; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Cardiac disorders/ Cardiac failure/ HEART FAILURE	2020-09-09 (7)/ 2020-09-12 (10)	Yes/ Yes/ No	2	Yes/3 (2020-09-09/ 2020-09-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: CONTINUING ON OXYGEN
Subject ID: US3822119; Age (years): 73; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-03 08:00 (21)/ 2020-09-06 (25)	Yes/ Yes/ No	3	Yes/3 (2020-09-04/ 2020-09-06)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832014; Age (years): 56; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Vascular disorders/ Hypertensive emergency/ HYPERTENSIVE EMERGENCY	2020-08-31 (4)/ 2020-09-02 (6)	Yes/ Yes/ No	3	Yes/3 (2020-08-31/ 2020-09-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832074; Age (years): 82; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Acute myocardial infarction/ ST ELEVATION MYOCARDIAL INFARCTION (UNSPECIFIED ARTERY)	2020-09-16 (44)/ 2020-09-18 (46)	Yes/ Yes/ No	3	Yes/3 (2020-09-16/ 2020-09-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832211; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/D							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ COPD EXACERBATION	2020-10-08 (24)/ 2020-10-16 (32)	Yes/ Yes/ No	3	Yes/3 (2020-10-08/ 2020-10-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862053; Age (years): 74; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-23 12:45 (32)/ 2020-10-31 (41)	Yes/ Yes/ No	3	Yes/3 (2020-10-23/ 2020-10-31)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872062; Age (years): 61; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Psychiatric disorders/ Confusional state/ CONFUSION	2020-10-18 (47)/ 2020-10-19 (48)	Yes/ Yes/ No	4	Yes/3 (2020-10-18/ 2020-10-23)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872062; Age (years): 61; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-10-18 (47)/ 2020-10-23 (52)	Yes/ Yes/ No	4	Yes/3 (2020-10-18/ 2020-10-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Sepsis/ SEPSIS	2020-10-18 (47)/ 2020-10-23 (52)	Yes/ Yes/ No	4	Yes/3 (2020-10-18/ 2020-10-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-18 (47)/ 2020-10-23 (52)	Yes/ Yes/ No	4	Yes/3 (2020-10-18/ 2020-10-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872324; Age (years): 41; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-10-11 (3)/ 2020-10-11 (3)	Yes/ Yes/ No	4	Yes/4	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECTS RIGHT FOOT IS IN A BOOT FOLLOWING SURGICAL REPAIR PROCEDURE
Injury, poisoning and procedural complications/ Ankle fracture/ CHIPPED BONE IN RT ANKLE	2020-10-11 (3)/ 2020-10-15 (7)	Yes/ Yes/ No	4	Yes/4	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872324; Age (years): 41; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Ligament rupture/ TORN LIGAMENTS IN RIGHT ANKLE	2020-10-11 (3)/ 2020-10-15 (7)	Yes/ Yes/ No	4	Yes/4	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3872402; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Foot fracture/ RIGHT FOOT FRACTURE (DUE TO MOTOR VEHICLE ACCIDENT)	2020-11-03 (36)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-03/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912028; Age (years): 75; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SC/SO							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS, LEFT SHOULDER	2020-09-28 (32)/ 2020-09-28 (32)	Yes/ No/ No	3	Yes/3 (2020-09-28/ 2020-09-29)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912241; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM, LLL	2020-11-03 (23)/ 2020-11-09 (29)	Yes/ Yes/ No	4	Yes/3 (2020-11-04/ 2020-11-05)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3922067; Age (years): 77; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Confusional state/ CONFUSION	2020-09-07 (7)/ 2020-09-09 (9)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-09)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3932005; Age (years): 79; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Gastrointestinal disorders/ Hiatus hernia/ HIATAL HERNIA	2020-10-20 (30)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-20/ 2020-10-22)	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932083; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Infections and infestations/ COVID-19/ COVID 19 POSITIVE	2020-11-14 (38)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-16/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN

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Serious Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932147; Age (years): 84; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Cardiac disorders/ Cardiac failure congestive/ WORSENING OF CONGESTIVE HEART FAILURE	2020-10-05 (20)/ 2020-10-11 (26)	Yes/ Yes/ No	4	Yes/3 (2020-10-05/ 2020-10-11)/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ EXACERBATED COPD CAUSED BY WORSENING CONGESTIVE HEART FAILURE	2020-10-05 (20)/ 2020-11-05 (51)	Yes/ Yes/ No	4	Yes/3 (2020-10-05/ 2020-10-11)/6	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932182; Age (years): 62; Sex: F; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]: SC							
Musculoskeletal and connective tissue disorders/ Cervical spinal stenosis/ C5-C6 SEVERE LEFT CANAL STENOSIS	2020-10-26 (7)/ 2020-11-17 (29)	Yes/ Yes/ No	3	Yes/3 (2020-10-26/ 2020-10-28)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932238; Age (years): 59; Sex: F; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]: D							
Infections and infestations/ COVID-19/ COVID-19	2020-11-07 (26)/ Ongoing	Yes/ No/ No	2	Yes/6	NR/ NR	DOSE DELAYED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3942151; Age (years): 54; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-10-13 (2)/ Ongoing	Yes/ No/ No	2	Yes/3 (2020-10-13/)	NR/ NR	DOSE DELAYED/ NONE	UNKNOWN

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3952033; Age (years): 52; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
Gastrointestinal disorders/ Food poisoning/ FOOD POISONING	2020-09-23 (22)/ 2020-09-30 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-23/ 2020-09-30)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Cardiac disorders/ Pericarditis/ PERICARDITIS	2020-10-31 (60)/ 2020-11-03 (63)	Yes/ No/ No	3	Yes/3 (2020-10-31/ 2020-11-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
		Yes/ Yes/ No	3	Yes/3 (2020-10-31/ 2020-11-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3972049; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION COMPLICATED	2020-11-15 (48)/ 2020-11-20 10:00 (52)	Yes/ Yes/ No	2	Yes/3 (2020-11-15/ 2020-11-20)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3982031; Age (years): 86; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-09-10 (15)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-25/ 2020-09-26)/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012098; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Gastrointestinal disorders/ Colitis/ COLITIS	2020-09-24 (17)/ 2020-09-30 (23)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Cardiac failure congestive/ EXACERBATION OF DIASTOLIC CHF	2020-09-29 (22)/ 2020-10-12 (35)	Yes/ Yes/ No	3	Yes/3 (2020-09-29/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012098; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ ACUTE HYPOXIC RESPIRATORY FAILURE	2020-09-29 (22)/ 2020-10-12 (35)	Yes/ Yes/ No	4	Yes/3 (2020-09-29/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Clostridium difficile infection/ CLOSTRICFIUM DIFFICILE	2020-09-29 (22)/ 2020-10-25 (48)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022031; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Pneumonia/ PNUEMONIA	2020-08-10 (15)/ 2020-08-19 (24)	Yes/ Yes/ No	4	Yes/3 (2020-08-10/ 2020-08-19)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Overdose/ OVERDOSE OF KLONOPIN	2020-08-10 (15)/ 2020-08-19 (24)	Yes/ Yes/ No	4	Yes/3 (2020-08-10/ 2020-08-19)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ LUNG FAILURE	2020-08-10 (15)/ 2020-08-19 (24)	Yes/ Yes/ No	4	Yes/3 (2020-08-10/ 2020-08-19)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022052; Age (years): 55; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Oesophageal carcinoma/ ESOPHAGEAL CANCER	2020-10-15 (35)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022103; Age (years): 59; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Abdominal pain upper/ INTERMITTENT EPIGASTRIC PAIN	2020-08-16 (17)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-08-16/ 2020-08-17)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022193; Age (years): 70; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Reproductive system and breast disorders/ Ovarian cyst/ OVARIAN CYSTS (RIGHT)	2020-09-17 05:00 (28)/ 2020-10-07 11:00 (48)	Yes/ Yes/ No	2	Yes/3 (2020-10-06/ 2020-10-07)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022208; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE	2020-09-10 (22)/ 2020-09-14 (26)	Yes/ Yes/ No	4	Yes/3 (2020-09-10/ 2020-09-14)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: DUE TO CONGESTIVE HEART FAILURE IS A NEW DIAGNOSIS.

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022246; Age (years): 62; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF LEFT HIP ARRHRITIS	2020-11-14 (52)/ 2020-11-15 (53)	Yes/ Yes/ No	4	Yes/3 (2020-11-14/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022276; Age (years): 45; Sex: F; Race: OTHER: (b) (6) Risk Factors for Severe COVID-19[4]: D							
Injury, poisoning and procedural complications/ Back injury/ WORSENING OF BACK INJURY	2020-10-02 (9)/ 2020-10-03 (10)	Yes/ Yes/ No	2	Yes/3 (2020-10-02/ 2020-10-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042190; Age (years): 27; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ MULTIPLE PULMONARY EMBOLI	2020-09-09 (28)/ 2020-09-10 (29)	Yes/ Yes/ No	2	Yes/3 (2020-09-09/ 2020-09-10)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3052028; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/D							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN NOS	2020-08-05 (7)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-05/ 2020-08-06)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062019; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
Infections and infestations/ Cellulitis/ CELLULITIS LEFT KNEE	2020-09-18 (22)/ 2020-09-26 (30)	Yes/ Yes/ No	4	Yes/3 (2020-09-22/ 2020-09-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: CONTINUES ON ANTIBIOTICS
Subject ID: US3062079; Age (years): 40; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Renal and urinary disorders/ Nephrolithiasis/ WORSENING OF NEPHROLITHIASIS RECURRENT	2020-09-07 (4)/ 2020-09-10 (7)	Yes/ Yes/ No	4	Yes/3 (2020-09-07/ 2020-09-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062151; Age (years): 72; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ LEFT HIP OSTEOARTHRITIS	2020-10-14 (41)/ 2020-10-15 (42)	Yes/ Yes/ No	4	Yes/3 (2020-10-14/ 2020-10-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Postoperative wound infection/ POST OP WOUND INFECTION	2020-10-20 (47)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-20/ 2020-10-28)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Alcohol abuse/ WORSENING OF ALCOHOL ABUSE	2020-09-17 (34)/ 2020-09-23 (40)	Yes/ Yes/ No	4	Yes/3 (2020-09-17/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST PAIN - MUSCULOSKELETAL	2020-10-13 (21)/ 2020-10-14 (22)	Yes/ Yes/ No	4	Yes/3 (2020-10-13/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Alcohol withdrawal syndrome/ ALCOHOL WITHDRAWAL SYMPTOMS	2020-10-13 (21)/ 2020-10-20 (28)	Yes/ Yes/ No	4	Yes/3 (2020-10-13/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Alcohol withdrawal syndrome/ ALCOHOL WITHDRAWAL SYMPTOMS	2020-10-27 (35)/ 2020-11-02 (41)	Yes/ Yes/ No	4	Yes/3 (2020-10-27/ 2020-11-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082051; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: L							
Gastrointestinal disorders/ Pancreatitis acute/ ACUTE PANCREATITIS	2020-08-26 (9)/ 2020-09-30 (44)	Yes/ Yes/ No	4	Yes/3 (2020-08-26/ 2020-09-30)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082051; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: L							
Hepatobiliary disorders/ Bile duct stone/ CHOLEDOCHOLITHIASIS	2020-08-26 (9)/ 2020-09-30 (44)	Yes/ Yes/ No	4	Yes/3 (2020-08-26/ 2020-09-30)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3082081; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2020-10-02 (12)/ 2020-10-19 (29)	Yes/ Yes/ No	3	Yes/3 (2020-10-02/ 2020-10-05)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3092022; Age (years): 57; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-03 (32)/ 2020-10-06 (35)	Yes/ Yes/ No	4	Yes/3 (2020-10-03/ 2020-10-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102061; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION WITH RVR	2020-08-20 (22)/ 2020-08-23 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-20 (22)/ 2020-08-23 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypertensive urgency/ HYPERTENSIVE URGENCY	2020-08-20 (22)/ 2020-08-23 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102082; Age (years): 65; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	2020-11-11 (76)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-11/ 2020-11-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112121; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant melanoma/ MELANOMA	2020-09-09 (8)/ 2020-09-21 (20)	Yes/ Yes/ No	4	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122010; Age (years): 62; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Lung cancer metastatic/ RECURRENCE OF THROAT CANCER WITH METASTASES TO LUNGS	2020-08-12 (17)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3132037; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-08 (40)/ Ongoing	Yes/ Yes/ No		Yes/3 (2020-11-14/)		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3132037; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-08 (40)/ Ongoing	Yes/ Yes/ No		Yes/3 (2020-11-14/)		DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	UNKNOWN
Subject ID: US3142185; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Volvulus/ INTESTINAL TORSION	2020-09-18 (3)/ 2020-09-26 (11)	Yes/ Yes/ No	3	Yes/3 (2020-09-18/ 2020-09-26)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3142268; Age (years): 60; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCER	2020-10-22 (23)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-22/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162003; Age (years): 75; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Cardiac disorders/ Acute myocardial infarction/ ACUTE MYOCARDIAL INFARCTION	2020-09-07 (15)/ 2020-09-08 (16)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-08/ 2020-09-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3162007; Age (years): 68; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Cerebrovascular accident/ MILD CEREBROVASCULAR ACCIDENT	2020-07-30 (4)/ 2020-07-31 (5)	Yes/ Yes/ No	3	Yes/3 (2020-07-30/ 2020-07-31)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172333; Age (years): 29; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Salpingitis/ BILATERAL ACUTE SALPINGITIS	2020-11-09 (47)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-09/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3192006; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-08-16 (16)/ 2020-08-17 (17)	Yes/ No/ No	2	Yes/3 (2020-08-16/ 2020-08-17)	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypotension/ HYPOTENSION	2020-08-16 (16)/ 2020-08-17 (17)	Yes/ Yes/ No	4	Yes/3 (2020-08-16/ 2020-08-17)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192345; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Pyelonephritis acute/ ACUTE PYELONEPHRITIS	2020-08-27 (5)/ 2020-09-04 (13)	Yes/ Yes/ No	4	Yes/3 (2020-08-28/ 2020-09-02)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urosepsis/ UROSEPSIS	2020-08-27 (5)/ 2020-09-04 (13)	Yes/ Yes/ No	4	Yes/3 (2020-08-28/ 2020-09-02)	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192486; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GI BLEED	2020-11-02 (41)/ 2020-11-08 (47)	Yes/ Yes/ No	3	Yes/3 (2020-11-02/ 2020-11-08)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED WITH SEQUELAE: COLONOSCOPY

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202191; Age (years): 77; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Infections and infestations/ Wound infection/ RIGHT ELBOW WOUND INFECTION	2020-10-27 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3202231; Age (years): 77; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Embolic stroke/ EMBOLIC STROKE	2020-10-31 (48)/ 2020-10-31 (48)	Yes/ Yes/ No	2	Yes/3 (2020-10-31/ 2020-11-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202310; Age (years): 63; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Hiatus hernia/ WORSENING OF HIATAL HERNIA	2020-10-06 (14)/ 2020-10-24 (32)	Yes/ Yes/ No	2	Yes/3 (2020-10-23/ 2020-10-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3212013; Age (years): 45; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Reproductive system and breast disorders/ Uterine haemorrhage/ ABNORMAL UTERINE BLEEDING	2020-08-27 (25)/ 2020-08-28 (26)	Yes/ Yes/ No	3	Yes/3 (2020-08-27/ 2020-08-28)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212013; Age (years): 45; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Reproductive system and breast disorders/ Uterine haemorrhage/ WORSENING OF ABNORMAL UTERINE BLEEDING	2020-09-22 (51)/ 2020-09-22 (51)	Yes/ No/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3212028; Age (years): 67; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Acute coronary syndrome/ ACUTE CORONARY SYNDROME (NON ST ELEVATED MYOCARDIAL INFARCTION)	2020-10-20 (50)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-23/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212326; Age (years): 46; Sex: F; Race: ASIAN; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Autonomic nervous system imbalance/ AUTONOMIC DYSFUNCTION	2020-10-18 (24)/ Ongoing	Yes/ Yes/ No	2	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222004; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Vascular disorders/ Hypertension/ UNCONTROLLED HYPERTENSION	2020-10-01 (22)/ 2020-10-02 (23)	Yes/ Yes/ No	4	Yes/3 (2020-10-01/ 2020-10-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222013; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-11-14 (72)/ 2020-11-16 (74)	Yes/ Yes/ No	3	Yes/3 (2020-11-14/ 2020-11-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222077; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2020-09-15 (7)/ 2020-10-02 (24)	Yes/ Yes/ No	4	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222299; Age (years): 57; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2020-10-03 (11)/ 2020-10-05 (13)	Yes/ Yes/ No	3	Yes/3 (2020-10-03/ 2020-10-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222388; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-09-25 (29)/ 2020-09-30 (34)	Yes/ Yes/ No	4	Yes/3 (2020-09-25/ 2020-09-30)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222388; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Injury, poisoning and procedural complications/ Incision site pain/ LUMBAR PAIN AT SURGERY SITE.	2020-10-08 (42)/ 2020-10-09 (43)	Yes/ Yes/ No	4	Yes/3 (2020-10-08/ 2020-10-09)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222452; Age (years): 80; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Cervical vertebral fracture/ C3 CERVICAL FRACTURE	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Facial bones fracture/ NASAL FRACTURE	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222452; Age (years): 80; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Skin laceration/ FACIAL LACERATION	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Subdural haematoma/ SUBDURAL HEMATOMA	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Fall/ FALL	2020-10-26 (25)/ 2020-10-30 (29)	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242017; Age (years): 64; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Bronchitis/ ACUTE BRONCHITIS	2020-10-17 (40)/ 2020-10-27 (50)	Yes/ Yes/ No	3	Yes/3 (2020-10-19/ 2020-10-21)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242231; Age (years): 76; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Vascular disorders/ Hypertension/ UNCONTROLLED HYPERTENSION	2020-09-08 (13)/ 2020-09-09 (14)	Yes/ Yes/ No	2	Yes/3 (2020-09-08/ 2020-09-09)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Aortic aneurysm/ WORSENING AORTIC ANEURYSM	2020-10-08 (14)/ 2020-10-28 (34)	Yes/ Yes/ No	3	Yes/3 (2020-10-27/ 2020-11-06)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242314; Age (years): 75; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATIC ADENOCARCINOMA (GLEASON SCORE 3+4+=7)	2020-11-06 (29)/ Ongoing	Yes/ Yes/ No	3	Yes/2	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242370; Age (years): 28; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Schizoaffective disorder/ WORSENING OF SCHIZOAFFECTIVE DISORDER	2020-09-29 (7)/ 2020-10-03 (11)	Yes/ Yes/ No	3	Yes/2/3 (2020-09-29/ 2020-10-03)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252127; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SC							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-10-28 (51)/ 2020-10-29 (52)	Yes/ Yes/ No	3	Yes/3 (2020-10-28/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3252166; Age (years): 50; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Endocrine disorders/ Thyroid disorder/ THYROIDECTOMY	2020-11-01 (53)/ 2020-11-01 (53)	Yes/ Yes/ No	3	Yes/3 (2020-10-30/ 2020-11-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252261; Age (years): 75; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SO							
Cardiac disorders/ Cardiac failure/ HEART FAILURE	2020-11-01 (47)/ 2020-11-03 (49)	Yes/ Yes/ No	4	Yes/3 (2020-11-01/ 2020-11-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252516; Age (years): 40; Sex: M; Race: OTHER: (b) (6) Risk Factors for Severe COVID-19[4]: D/L							
Gastrointestinal disorders/ Colitis/ COLITIS	2020-09-30 00:00 (9)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-30/ 2020-10-08)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-30 00:00 (9)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-30/ 2020-10-08)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272169; Age (years): 47; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Rectal prolapse/ RECTAL PROLAPSE	2020-09-08 (25)/ 2020-09-08 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-19/ 2020-10-24)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272169; Age (years): 47; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Rectal prolapse/ RECTAL PROLAPSE REPAIR COMPLICATION DUE TO CONSTIPATION	2020-11-05 (51)/ 2020-11-07 (53)	Yes/ Yes/ No	3	Yes/3 (2020-11-05/ 2020-11-07)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282113; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-10-23 (8)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-23/ 2020-10-25)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282113; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY THROMBOEMBOLISM	2020-11-06 (22)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-06/ 2020-11-10)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292023; Age (years): 80; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D							
Metabolism and nutrition disorders/ Diabetic ketoacidosis/ DIABETIC KETOACIDOSIS	2020-10-22 (52)/ 2020-10-26 (56)	Yes/ Yes/ No	3	Yes/3 (2020-10-22/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292103; Age (years): 65; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Subdural haematoma/ SUBDURAL HEMATOMA	2020-11-14 (71)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-15/ 2020-11-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3292304; Age (years): 35; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Large intestine perforation/ PERFORATED COLON	2020-10-04 (13)/ 2020-10-06 (15)	Yes/ Yes/ No	3	Yes/3 (2020-10-04/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292304; Age (years): 35; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2020-10-07 (16)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-04/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292312; Age (years): 56; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D							
Nervous system disorders/ Cerebrovascular accident/ STROKE	2020-10-25 (34)/ 2020-10-25 (34)	Yes/ Yes/ No	4	Yes/3 (2020-10-25/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3292324; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Injury, poisoning and procedural complications/ Femur fracture/ R BROKEN FEMUR	2020-11-03 (41)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292365; Age (years): 58; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Invasive lobular breast carcinoma/ INVASIVE LOBULAR BREAST CARCINOMA	2020-10-08 (13)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3302212; Age (years): 34; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Cervical radiculopathy/ WORSENING CERVICAL RADICULOPATHY	2020-09-28 (18)/ 2020-09-30 (20)	Yes/ No/ No	2	Yes/3 (2020-09-28/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312046; Age (years): 82; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Viral pharyngitis/ VIRAL PHARYNGITIS	2020-10-07 (29)/ 2020-11-15 (68)	Yes/ Yes/ No	2	Yes/3 (2020-10-07/ 2020-10-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312637; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL							
Cardiac disorders/ Coronary artery disease/ EXACERBATION OF CORONARY ARTERY DISEASE	2020-10-15 (35)/ 2020-10-16 (36)	Yes/ Yes/ No	2	Yes/3 (2020-10-15/ 2020-10-16)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3322302; Age (years): 37; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Injury, poisoning and procedural complications/ Wrist fracture/ RIGHT SCAPHOID FRACTURE	2020-10-22 (15)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322329; Age (years): 51; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
General disorders and administration site conditions/ Swelling face/ FACIAL SWELLING	2020-10-17 (3)/ 2020-10-22 (8)	Yes/ Yes/ No	3	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322353; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE ADENOCARCINOMA	2020-10-16 (4)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342281; Age (years): 42; Sex: M; Race: OTHER: (b) (6) Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION	2020-10-27 04:30 (33)/ 2020-11-20 10:00 (57)	Yes/ Yes/ No	2	Yes/3 (2020-10-29/ 2020-10-30)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352299; Age (years): 48; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Skin and subcutaneous tissue disorders/ Rash vesicular/ DISSEMINATED VESICULAR RASH ALL OVER BODY	2020-11-08 (41)/ 2020-11-13 (46)	Yes/ Yes/ No	4	Yes/3 (2020-11-08/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ RASH SKIN ERUPTION	2020-11-11 (44)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Serious Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352299; Age (years): 48; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Investigations/ Transaminases increased/ ELEVATED TRANSAMINASE LEVEL	2020-11-11 (44)/ 2020-11-13 (46)	Yes/ Yes/ No	4	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362222; Age (years): 51; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2020-10-09 (8)/ 2020-10-11 (10)	Yes/ Yes/ No	4	Yes/3 (2020-10-10/ 2020-10-11)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362244; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Musculoskeletal and connective tissue disorders/ Fracture nonunion/ WORSENING OF ANTERIOR LEFT PELVIC RING NON-UNION	2020-09-09 (17)/ 2020-10-05 (43)	Yes/ Yes/ No	4	Yes/3 (2020-09-29/ 2020-10-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Postoperative abscess/ POST OPERATIVE INTRA-ABDOMINAL ABSCESS	2020-10-12 (50)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-12/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362244; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Vascular disorders/ Axillary vein thrombosis/ RIGHT AXILLARY DEEP VEIN THROMBOSIS	2020-10-19 (57)/ Ongoing	Yes/ Yes/ No	4	Yes/2	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Vascular disorders/ Deep vein thrombosis/ RIGHT BRACHIAL DEEP VEIN THROMBOSIS	2020-10-19 (57)/ Ongoing	Yes/ Yes/ No	4	Yes/2	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3362285; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: D							
Nervous system disorders/ Cerebrovascular accident/ CEREBROVASCULAR ACCIDENT	2020-11-16 (26)/ 2020-11-18 (28)	Yes/ Yes/ No	4	Yes/2/3 (2020-11-16/ 2020-11-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372394; Age (years): 68; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Vascular disorders/ Arteriosclerosis/ SYMPTOMATIC ATHEROSCLEROTIC DISEASE.	2020-11-11 (34)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382284; Age (years): 45; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Gastric cancer/ GASTRIC CANCER	2020-10-29 (44)/ Ongoing	Yes/ Yes/ No	3	Yes/2/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3392120; Age (years): 63; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-24 (25)/ 2020-10-26 (27)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3392149; Age (years): 30; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Hepatitis A/ HEPATITIS A	2020-09-24 (23)/ 2020-09-25 (24)	Yes/ Yes/ No	3	Yes/3 (2020-09-24/ 2020-09-25)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402042; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SC							
Respiratory, thoracic and mediastinal disorders/ Emphysema/ WORSENING OF EMPHYSEMA	2020-10-01 (38)/ 2020-10-17 (54)	Yes/ Yes/ No	2	Yes/3 (2020-10-13/ 2020-10-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402139; Age (years): 55; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING LEFT KNEE ARTHRITIS	2020-08-09 (9)/ 2020-10-14 (75)	Yes/ Yes/ No	2	Yes/3 (2020-10-12/ 2020-10-14)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT UNDERGOING PHYSICAL THERAPY

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402212; Age (years): 79; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ WORSENING SPINAL STENOSIS	2020-08-23 (20)/ 2020-09-29 (57)	Yes/ Yes/ No	3	Yes/3 (2020-08-23/ 2020-08-25)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3402284; Age (years): 58; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-09-22 (13)/ 2020-09-23 (14)	Yes/ Yes/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412013; Age (years): 58; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Injury, poisoning and procedural complications/ Animal bite/ CATBITE	2020-11-20 (87)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-22/)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3412125; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Blood and lymphatic system disorders/ Blood loss anaemia/ ACUTE POST HEMORRHAGIC ANEMIA	2020-09-08 (8)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT	2020-09-08 (8)/ 2020-09-08 (8)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412125; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Cervical vertebral fracture/ CERVICAL 7 FRACTURE	2020-09-09 (9)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Traumatic liver injury/ GRADE IV LIVER LACERATION	2020-09-09 (9)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	UNKNOWN
Nervous system disorders/ Embolic stroke/ MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT	2020-09-09 (9)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN

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Serious Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412125; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Pneumonia staphylococcal/ MRSA PNEUMONIA	2020-09-09 (9)/ 2020-09-29 (29)	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Coronary artery thrombosis/ LEFT INTERCAROTID ARTERY DISSECTION WITH INTRALUMINAL THROMBUS	2020-09-13 (13)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412125; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Acute myocardial infarction/ NON STEMI VS CARDIAC CONTUSION	2020-09-13 (13)/ 2020-10-01 (31)	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Craniocerebral injury/ TRAUMATIC BRAIN INJURY	2020-09-23 (23)/ 2020-10-01 (31)	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: FUNCTION OF SUBJECT CONFUSION, WEAKNESS

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412126; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-08-23 (20)/ 2020-11-14 (103)	Yes/ Yes/ No	4	Yes/3 (2020-08-23/ 2020-09-01)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3412127; Age (years): 42; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE RESPIRATORY FAILURE	2020-08-14 (10)/ 2020-08-20 (16)	Yes/ No/ No	4	Yes/3 (2020-08-16/ 2020-08-20)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422135; Age (years): 67; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ SPINAL STENOSIS	2020-10-06 (12)/ 2020-10-08 (14)	Yes/ Yes/ No	3	Yes/3 (2020-10-06/ 2020-10-08)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432016; Age (years): 76; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GERD	2020-10-22 (51)/ 2020-10-24 (53)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432094; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Meningioma/ CRANIOPLASTY AND CRANIECTOMY FOR MENINGIOMA	2020-11-23 (75)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-23/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432229; Age (years): 24; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Psychiatric disorders/ Intentional self-injury/ SELF- INJURIOUS BEHAVIOR	2020-10-17 (30)/ 2020-10-30 (43)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-30)/6	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432242; Age (years): 70; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Chronic lymphocytic leukaemia/ CLL - CHRONIC LYMPHOCYTIC LEUKEMIA	2020-10-08 (18)/ Ongoing	Yes/ Yes/ No	2	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432392; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ BENIGN PROSTATIC HYPERPLASIA (BPH) S/P TRANSURETHRAL RESECTION OF THE PROSTATE (TURP)	2020-10-19 (21)/ 2020-10-20 (22)	Yes/ Yes/ No	3	Yes/3 (2020-10-19/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432627; Age (years): 33; Sex: F; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]:							
General disorders and administration site conditions/ Hernia/ HERNIA S/P LEFT INGUINAL HERNIA REPAIR	2020-11-23 (6)/ 2020-11-24 (7)	Yes/ Yes/ No	3	Yes/3 (2020-11-23/ 2020-11-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442031; Age (years): 55; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2020-11-03 (44)/ 2020-11-04 (45)	Yes/ Yes/ No	3	Yes/3 (2020-11-03/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Deep vein thrombosis/ DEEP VEIN THROMBOSIS (LEFT LEG)	2020-11-03 (44)/ 2020-11-04 (45)	Yes/ Yes/ No	3	Yes/3 (2020-11-03/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442113; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-09-02 21:00 (2)/ 2020-09-04 10:51 (3)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3462091; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SC/SO/D							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-10-09 (32)/ 2020-10-14 (37)	Yes/ Yes/ No	4	Yes/3 (2020-10-09/ 2020-10-14)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462101; Age (years): 45; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Transient ischaemic attack/ TRANSIENT ISCHEMIC ATTACK	2020-09-25 06:00 (15)/ 2020-09-25 18:00 (16)	Yes/ Yes/ No	4	Yes/3 (2020-09-25/ 2020-09-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462133; Age (years): 61; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Seizure/ GENERALIZED SEIZURES	2020-08-23 (12)/ 2020-08-26 (15)	Yes/ Yes/ No	4	Yes/3 (2020-08-23/ 2020-08-26)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472013; Age (years): 59; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Respiratory, thoracic and mediastinal disorders/ Atelectasis/ ATELECTASIS	2020-09-21 (20)/ 2020-09-24 (23)	Yes/ Yes/ No	4	Yes/3 (2020-09-21/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482023; Age (years): 70; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	2020-11-04 (42)/ 2020-11-05 (43)	Yes/ Yes/ No	4	Yes/3 (2020-11-04/ 2020-11-05)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482284; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-28 (13)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-05/ 2020-11-07)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-28 (13)/ 2020-10-31 (16)	Yes/ Yes/ No	4	Yes/2/3 (2020-10-29/ 2020-10-31)/4	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SHORTNESS OF BREATH & IMPAIRED CARDIAC FUNCTION (CHF)

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482284; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC							
Cardiac disorders/ Acute left ventricular failure/ ACUTE ON CHRONIC SYSTOLIC HEART FAILURE	2020-11-05 (21)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-05/ 2020-11-07)/4	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chest pain/ CHEST PAIN	2020-11-16 (32)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-18/)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492078; Age (years): 93; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Vascular disorders/ Haematoma/ HEMATOMA OF THE R LEG	2020-11-03 (33)/ 2020-11-11 (41)	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3492243; Age (years): 50; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-07 (18)/ Ongoing	Yes/ Yes/ No	1	Yes/6	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512042; Age (years): 78; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Cardio-respiratory arrest/ CARDIOPULMONARY ARREST	2020-09-01 (21)/ 2020-09-01 (21)	Yes/ Yes/ No	4	Yes/1	NR/ NR	DOSE NOT CHANGED/ NONE	FATAL

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512193; Age (years): 77; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-10-27 (26)/ Ongoing	Yes/ Yes/ Yes	3	Yes/3 (2020-10-27/ 2020-10-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522529; Age (years): 44; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Musculoskeletal and connective tissue disorders/ Intervertebral disc degeneration/ DEGENERATIVE DISC DISEASE (MULTILEVEL)	2020-09-21 (20)/ 2020-09-23 (22)	Yes/ Yes/ No	4	Yes/3 (2020-09-21/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532002; Age (years): 63; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING BACK PAIN	2020-09-08 (1)/ 2020-10-14 (37)	Yes/ Yes/ No	4	Yes/3 (2020-09-16/ 2020-09-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3532192; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Renal cancer/ KIDNEY CANCER	2020-10-09 (4)/ Ongoing	Yes/ Yes/ No	3	Yes/2/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532231; Age (years): 76; Sex: M; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]:							
Infections and infestations/ Pneumonia/ COMMUNITY ACQUIRED PNEUMONIA	2020-10-10 (10)/ 2020-10-16 (16)	Yes/ Yes/ No	4	Yes/3 (2020-10-10/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Toxic encephalopathy/ TOXIC ENCEPHALOPATHY	2020-10-10 (10)/ 2020-10-16 (16)	Yes/ Yes/ No	4	Yes/3 (2020-10-10/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532281; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Surgical and medical procedures/ Ankle arthroplasty/ LEFT ANKLE REPLACEMENT	2020-10-23 (18)/ 2020-10-25 (20)	Yes/ Yes/ No	4	Yes/3 (2020-10-23/ 2020-10-25)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3542108; Age (years): 46; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
General disorders and administration site conditions/ Swelling face/ CHEEK SWELLING, BILATERAL	2020-09-30 10:00 (1)/ 2020-10-05 (7)	Yes/ Yes/ No	2	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542309; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Subarachnoid haemorrhage/ SUBARACHNOID HEMORRHAGE	2020-11-13 (17)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-13/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542332; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Seizure/ EXACERBATION OF SEIZURE DISORDER	2020-11-07 (30)/ 2020-11-08 (31)	Yes/ Yes/ No	3	Yes/3 (2020-11-07/ 2020-11-08)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552024; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN, NON-SPECIFIED	2020-08-24 (12)/ 2020-09-11 (30)	Yes/ Yes/ No	3	Yes/3 (2020-08-29/ 2020-08-30)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552053; Age (years): 65; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-15 12:00 (1)/ 2020-09-21 (8)	Yes/ Yes/ Yes	4	Yes/3 (2020-09-17/ 2020-09-18)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ INTRACTABLE VOMITING	2020-09-15 12:00 (1)/ 2020-09-21 (8)	Yes/ Yes/ Yes	4	Yes/3 (2020-09-17/ 2020-09-18)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552191; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH ON EXERTION	2020-09-30 (8)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-09/ 2020-10-10)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552191; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D							
General disorders and administration site conditions/ Oedema peripheral/ BILATERAL ANKLE EDEMA	2020-10-06 (14)/ 2020-10-31 (39)	Yes/ No/ No	4	Yes/3 (2020-10-09/ 2020-10-10)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552371; Age (years): 56; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Renal cell carcinoma/ RIGHT KIDNEY RENAL CELL CARCINOMA	2020-10-08 (31)/ 2020-11-13 (67)	Yes/ Yes/ No	4	Yes/3 (2020-11-12/ 2020-11-13)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562157; Age (years): 62; Sex: F; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Colorectal cancer/ COLORECTAL CANCER	2020-11-04 (22)/ Ongoing	Yes/ Yes/ No	4	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Pelvic neoplasm/ PELVIC CANCER	2020-11-04 (22)/ Ongoing	Yes/ Yes/ No	4	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562230; Age (years): 45; Sex: M; Race: OTHER: (b) (6) Risk Factors for Severe COVID-19[4]: SO							
Hepatobiliary disorders/ Hepatic mass/ LIVER NODULE	2020-11-07 (24)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-07/ 2020-11-17)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3592111; Age (years): 73; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Diverticular perforation/ PERFORATED DIVERTICULITIS	2020-11-03 (58)/ Ongoing	Yes/ Yes/ Yes	2	Yes/3 (2020-11-05/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592232; Age (years): 79; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Femoral neck fracture/ RIGHT SUBCAPITAL FEMORAL NECK FRACTURE, DISPLACED GARDEN III	2020-08-25 (6)/ 2020-10-05 (47)	Yes/ Yes/ No	3	Yes/3 (2020-08-25/ 2020-08-28)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3592247; Age (years): 87; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-11-10 (46)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-10/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3682134; Age (years): 46; Sex: M; Race: OTHER: (b) (6) Risk Factors for Severe COVID-19[4]: SO/D							
Nervous system disorders/ Syncope/ SYNCOPE, WORSENED FROM BASELINE	2020-09-21 (5)/ 2020-09-24 (8)	Yes/ No/ No	4	Yes/3 (2020-09-21/ 2020-09-24)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722406; Age (years): 63; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Constipation/ SEVERE CONSTIPATION		Yes/ No/ No	2	Yes/3	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3722406; Age (years): 63; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ BPH		Yes/ No/ No	2	Yes/3	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742169; Age (years): 57; Sex: M; Race: ASIAN; Risk Factors for Severe COVID-19[4]: CL							
Musculoskeletal and connective tissue disorders/ Rheumatoid arthritis/ RHEUMATOID ARTHRITIS	2020-08-31 23:00 (1)/ Ongoing	Yes/ Yes/ No	2	Yes/6	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3752129; Age (years): 46; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Papillary thyroid cancer/ PAPILLARY THYROID CARCINOMA	2020-10-01 (11)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-02/ 2020-10-03)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	UNKNOWN
Surgical and medical procedures/ Thyroidectomy/ TOTAL THYROIDECTOMY	2020-10-02 (12)/ 2020-10-02 (12)	Yes/ Yes/ No	4	Yes/3 (2020-10-02/ 2020-10-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752153; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Surgical and medical procedures/ Knee arthroplasty/ TOTAL RIGHT KNEE ARTHROPLASTY REQUIRING HOSPITALIZATION	2020-11-10 (56)/ 2020-11-10 (56)	Yes/ Yes/ No	4	Yes/3 (2020-11-10/ 2020-11-11)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752173; Age (years): 77; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-11-01 (45)/ 2020-11-01 (45)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ NONE	FATAL
Subject ID: US3752245; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/D							
Nervous system disorders/ Facial paralysis/ BELL'S PALSY	2020-11-06 (32)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-06/ 2020-11-07)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762161; Age (years): 74; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-09 (41)/ 2020-11-15 (47)	Yes/ Yes/ No	3	Yes/2/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dehydration/ [DIARRHEA WITH] DEHYDRATION	2020-11-09 (41)/ 2020-11-15 (47)	Yes/ Yes/ No	2	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Sepsis/ SEPSIS	2020-11-10 (42)/ Ongoing	Yes/ Yes/ No	3	Yes/2/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762161; Age (years): 74; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-11-10 (42)/ 2020-11-11 (43)	Yes/ Yes/ No	3	Yes/2/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-11-10 (42)/ 2020-11-15 (47)	Yes/ Yes/ No	2	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	2020-11-10 (42)/ 2020-11-15 (47)	Yes/ Yes/ No	1	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762161; Age (years): 74; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Metabolism and nutrition disorders/ Hyponatraemia/ ACUTE HYPONATREMIA	2020-11-10 (42)/ 2020-11-15 (47)	Yes/ Yes/ No	1	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Pneumonia/ LEFT UPPER LOBE PNEUMONIA	2020-11-10 (42)/ 2020-11-18 (50)	Yes/ Yes/ No	3	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772037; Age (years): 72; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE HYPOXIC RESPIRATORY FAILURE DUE TO COVID-19 INFECTION	2020-11-07 (61)/ 2020-11-12 (66)	Yes/ Yes/ No	4	Yes/3 (2020-11-08/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782162; Age (years): 78; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC							
Cardiac disorders/ Acute coronary syndrome/ ACUTE CORONARY SYNDROME	2020-09-21 (14)/ 2020-09-21 (14)	Yes/ Yes/ No	4	Yes/3 (2020-09-21/ 2020-09-24)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802218; Age (years): 64; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D/H							
Gastrointestinal disorders/ Hiatus hernia/ PARAESOPHOGEAL HIATAL HERNIA WORSENING	2020-10-28 (16)/ 2020-11-05 (24)	Yes/ Yes/ No	2	Yes/3 (2020-10-28/ 2020-11-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812098; Age (years): 67; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-08-28 (19)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822003; Age (years): 65; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-24 (54)/ 2020-10-27 (57)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-27)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Cardiac disorders/ Pericarditis/ ACUTE PERICARDITIS	2020-11-12 (73)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-12/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822043; Age (years): 75; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ B-cell small lymphocytic lymphoma/ SMALL LYMPHOCYTIC LYMPHOMA	2020-10-06 11:00 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/6	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822278; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/D							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-09-26 15:00 (1)/ 2020-09-28 (4)	Yes/ No/ No	2	Yes/3 (2020-09-26/ 2020-09-28)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832043; Age (years): 29; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
Infections and infestations/ Toxic shock syndrome/ SUSPECTED TOXIC SHOCK SYNDROME	2020-08-23 (22)/ 2020-08-25 (24)	Yes/ Yes/ No	3	Yes/3 (2020-08-23/ 2020-08-25)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832055; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Nervous system disorders/ Syncope/ SYNCOPAL EPISODE	2020-09-20 (12)/ 2020-09-23 (15)	Yes/ Yes/ No	3	Yes/3 (2020-09-20/ 2020-09-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862021; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC/D							
Cardiac disorders/ Myocardial infarction/ INFEROLATERAL STEMI	2020-10-04 00:45 (20)/ 2020-10-07 (24)	Yes/ Yes/ No	4	Yes/2/3 (2020-10-04/ 2020-10-07)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3872090; Age (years): 63; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA UNSPECIFIED TYPE	2020-08-11 (5)/ 2020-09-14 (39)	Yes/ Yes/ No	3	Yes/3 (2020-08-18/ 2020-08-22)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872118; Age (years): 36; Sex: F; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]: SO/D							
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2020-11-15 (69)/ 2020-11-15 (69)	Yes/ Yes/ No	4	Yes/3 (2020-11-15/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3872318; Age (years): 62; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Psychiatric disorders/ Completed suicide/ SUICIDE	2020-09-16 (21)/ 2020-09-16 (21)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ NONE	FATAL
Subject ID: US3912024; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Intestinal perforation/ BOWEL PERFORATION	/ 2020-11-08 (73)	Yes/ Yes/ No	3	Yes/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912024; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Musculoskeletal and connective tissue disorders/ Flank pain/ FLANK PAIN (LEFT)	2020-11-03 (41)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE	2020-11-12 (50)/ Ongoing	Yes/ Yes/ No	3	Yes/2/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912114; Age (years): 74; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Humerus fracture/ BROKEN RIGHT HUMERUS (RELATED TO FALL)	2020-10-30 (57)/ 2020-11-10 (68)	Yes/ Yes/ No	4	Yes/3 (2020-11-10/ 2020-11-11)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3932077; Age (years): 29; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Gastrointestinal disorders/ Abdominal pain upper/ SEVERE STOMACH CRAMPING	2020-11-06 (36)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	
Gastrointestinal disorders/ Nausea/ INTERMITTENT NAUSEA	2020-11-06 (36)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3942021; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:							
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT TRAUMA	2020-09-06 (10)/ 2020-10-01 (35)	Yes/ No/ No	3	Yes/3 (2020-09-06/ 2020-09-22)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3952104; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL							
Injury, poisoning and procedural complications/ Hip fracture/ HIP FRACTURE	2020-10-05 (19)/ 2020-10-08 (22)	Yes/ Yes/ No	3	Yes/3 (2020-10-07/ 2020-10-12)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3962063; Age (years): 57; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D							
Injury, poisoning and procedural complications/ Tendon rupture/ TORN TENDON LEFT ANKLE	2020-10-02 (2)/ 2020-10-31 (31)	Yes/ Yes/ No	4	Yes/3 (2020-10-30/ 2020-10-31)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962094; Age (years): 56; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO							
Injury, poisoning and procedural complications/ Head injury/ HEAD TRAUMA	2020-10-15 (37)/ 2020-10-15 (37)	Yes/ No/ No	4	Yes/1	NR/ NR	DOSE NOT CHANGED/ NONE	FATAL
Subject ID: US3972064; Age (years): 69; Sex: F; Race: MULTIPLE: (b) (6) Risk Factors for Severe COVID-19[4]: CL/SC							
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE EXACERBATION	2020-09-02 06:45 (2)/ 2020-09-05 17:00 (6)	Yes/ Yes/ No	2	Yes/3 (2020-09-02/ 2020-09-05)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3982272; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:							
Cardiac disorders/ Atrial fibrillation/ NEW ONSET ATRIAL FIBRILLATION	2020-10-20 (8)/ 2020-10-27 (15)	Yes/ Yes/ No	3	Yes/3 (2020-10-20/ 2020-10-22)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9
Serious Adverse Events
Safety Set

TEAE = Treatment-Emergent Adverse Event; MAAE = Medically-Attended Adverse Event; AR = Adverse Reaction; SAE = Serious Adverse Event; IP = Investigational Product; SP = Study Procedure.
Relative day is defined as days from the most recent injection date.
MedDRA version 23.0.
[1] Sev. = Severity, 1 = Grade 1/Mild, 2 = Grade 2/Moderate, 3 = Grade 3/Severe, 4 = Grade 4.
[2] 1 = Death, 2 = Life threatening, 3 = Requires inpatient or prolongation of existing Hospitalization (Hospital Admission Date/ Hospital Discharge Date), 4 = Persistent or significant disability or incapacity, 5 = Congenital anomaly or birth defect, 6 = Other medically important event.
[3] R = Related, NR = Not Related, NA = Not Applicable.
[4] CL = Chronic Lung Disease, SC = Significant Cardiac Disease, SO = Severe Obesity, D = Diabetes, L = Liver Disease, H = Human Immunodeficiency Virus Infection.

Listing 16.2.7.11
Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002031; Age (years): 25; Sex: F; Race: MULTIPLE:				(b) (6)			
Infections and infestations/ COVID-19/ COVID-19	2020-09-18 (53)/ 2020-10-21 (86)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3002046; Age (years): 60; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Hip fracture/ LEFT BROKEN HIP	2020-08-12 (15)/ 2020-08-14 (17)	Yes/ Yes/ No	3	Yes/3 (2020-08-12/)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3002302; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-07 (23)/ 2020-10-17 (33)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032171; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-10 (32)/ 2020-09-24 (46)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.11
Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032172; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-09-01 (23)/ 2020-09-08 (30)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042209; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-08 (26)/ 2020-10-06 (54)	Yes/ Yes/ No	1	No	NR/ NA	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082247; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-10-13 (28)/ 2020-10-22 (37)	Yes/ No/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112266; Age (years): 28; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 DIAGNOSIS	2020-09-06 (24)/ 2020-09-26 (44)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112267; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 DIAGNOSIS	2020-09-06 (24)/ 2020-09-17 (35)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152025; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-14 (17)/ 2020-08-27 (30)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: COUGH
Subject ID: US3162159; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-20 19:00 (1)/ 2020-09-03 06:30 (14)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172038; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ Pyelonephritis acute/ ACUTE PYELONEPHRITIS (RIGHT KIDNEY)	2020-09-01 (22)/ 2020-09-26 (47)	Yes/ No/ No	4	Yes/2/3 (2020-09-01/ 2020-09-04)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.11
Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172069; Age (years): 68; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-09-04 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172185; Age (years): 61; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172467; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 SYMPTOMATIC	2020-10-29 (9)/ 2020-11-07 (18)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3182292; Age (years): 19; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-08-23 (13)/ 2020-08-28 (18)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222424; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SARS COVID-19	2020-09-10 (11)/ 2020-10-05 (36)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Throat tightness/ TIGHT THROAT	2020-09-10 (11)/ 2020-10-09 (40)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242258; Age (years): 76; Sex: F; Race: WHITE							
Infections and infestations/ Pneumonia/ COMMUNITY ACQUIRED PNEUMONIA	2020-09-15 (16)/ 2020-10-22 (53)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252020; Age (years): 24; Sex: M; Race: NOT REPORTED							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-08-13 (10)/ 2020-08-22 (19)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252638; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-24 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3302383; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-22 (28)/ 2020-09-29 (35)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE RESPIRATORY FAILURE	2020-09-26 (32)/ 2020-09-28 (34)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-28)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312068; Age (years): 21; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-08-17 (5)/ 2020-08-28 (16)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312201; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-08-24 (5)/ 2020-10-09 (51)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312210; Age (years): 50; Sex: M; Race: WHITE							
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-11-06 (50)/ 2020-11-06 (50)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312212; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Osteomyelitis/ LEFT GREAT TOE OSTEOMYELITIS	2020-09-04 (15)/ 2020-10-16 (57)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-09)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: RECOVERED WITH SEQUALAE LEFT GREAT TOE AMPUTATION
Subject ID: US3312548; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-03 (26)/ 2020-10-15 (38)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312587; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-03 (25)/ 2020-10-20 (42)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322006; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-09-09 (24)/ 2020-10-06 (51)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322061; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-09-07 (18)/ 2020-09-15 (26)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332060; Age (years): 43; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Migraine/ WORSENING OF MIGRIANES	2020-08-25 11:00 (1)/ 2020-08-27 11:00 (3)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342088; Age (years): 50; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Colon cancer stage III/ STAGE III COLON CANCER	2020-09-15 (30)/ Ongoing	Yes/ Yes/ No	2	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342253; Age (years): 24; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pleurisy/ IDIOPATHIC PLEURISY RECURRENCE	2020-09-18 (8)/ 2020-10-19 (39)	Yes/ Yes/ No	2	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342259; Age (years): 41; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression suicidal/ DEPRESSION WITH SUICIDAL IDEATION	2020-10-14 (31)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342343; Age (years): 61; Sex: F; Race: UNKNOWN							
Musculoskeletal and connective tissue disorders/ Synovitis/ NEW ONSET OF SYMMETRICAL SYNOVITIS OF HANDS AND FEET	2020-10-26 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3352072; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-08-19 (7)/ 2020-09-04 (23)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362083; Age (years): 18; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-08-28 (21)/ 2020-09-06 (30)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372110; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-08-31 (19)/ 2020-09-14 (33)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402430; Age (years): 57; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-14 (24)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3412328; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ ATYPICAL CHEST PAIN	2020-09-17 (23)/ 2020-09-18 (24)	Yes/ Yes/ No	4	Yes/3 (2020-09-17/ 2020-09-18)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432023; Age (years): 83; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Polymyalgia rheumatica/ POSSIBLE POLYMYALGIA RHEUMATICA	2020-08-20 (16)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-21)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3452295; Age (years): 62; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-08-06 16:40 (1)/ 2020-08-25 (20)	No/ Yes/ No	1	No	NA/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472096; Age (years): 42; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3472130; Age (years): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-11-03 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3492117; Age (years): 61; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ COVID-19/ COVID 19, CONFIRMED	2020-09-22 (13)/ 2020-10-05 (26)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492242; Age (years): 29; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-09-29 (7)/ 2020-10-22 (30)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-30 10:00 (2)/ Ongoing	Yes/ No/ Yes	3	No	R/ R	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES ON FACE AND NECK	2020-08-31 (3)/ Ongoing	Yes/ No/ No	1	No	R/ R	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-31 (3)/ 2020-09-20 (23)	Yes/ No/ Yes	3	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES (FACE AND NECK)	2020-08-31 (3)/ 2020-10-04 (37)	Yes/ No/ No	1	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ INTERMITTENT FATIGUE	2020-09-19 (22)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHES	2020-09-23 (26)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES (FACE AND NECK)	2020-10-08 (41)/ Ongoing	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522042; Age (years): 34; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-22 (16)/ 2020-08-30 (24)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522297; Age (years): 63; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19 INFECTION	2020-09-18 (29)/ 2020-09-26 (37)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532020; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ulnar nerve injury/ ULNAR NERVE IRRITATION	2020-08-16 (4)/ 2020-10-15 (64)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532170; Age (years): 66; Sex: F; Race: WHITE							
Cardiac disorders/ Acute myocardial infarction/ ACUTE MYOCARDIAL INFARTION	2020-09-06 (11)/ 2020-10-06 (41)	Yes/ Yes/ No	4	Yes/3 (2020-09-06/ 2020-10-06)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3542043; Age (years): 26; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-09-07 (15)/ 2020-09-14 (22)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542090; Age (years): 65; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ POLYARTHRALGIAS	2020-09-03 (7)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542168; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Anxiety/ ANXIETY EXACERBATION	2020-09-19 (16)/ 2020-09-23 (20)	Yes/ Yes/ No	3	Yes/3 (2020-09-19/ 2020-09-23)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552087; Age (years): 65; Sex: M; Race: WHITE							
Cardiac disorders/ Palpitations/ INCREASED HEART PALPITATIONS	2020-09-12 (25)/ 2020-10-16 (59)	Yes/ Yes/ No	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552103; Age (years): 51; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-09-03 (15)/ 2020-10-12 (54)	Yes/ No/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552140; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Eye disorders/ Retinal detachment/ RETINAL DETACHMENT OF LEFT EYE	2020-09-08 (18)/ 2020-09-12 (22)	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE	2020-09-28 (31)/ 2020-11-19 (83)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552273; Age (years): 52; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-09-01 14:07 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3552331; Age (years): 44; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-09-15 (12)/ 2020-10-01 (28)	Yes/ Yes/ No	4	Yes/3 (2020-09-16/ 2020-09-21)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552444; Age (years): 74; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ WORSENING ATRIAL FIBRILLATION ARRHYTHMIA	2020-10-01 (16)/ 2020-10-16 (31)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602008; Age (years): 62; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural anxiety/ ANXIETY DUE THE SIDE EFFECTS OF THE FIRST IP	2020-09-08 (7)/ 2020-09-30 (29)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	UNKNOWN
Subject ID: US3602111; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-10-24 (26)/ 2020-11-23 (56)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622012; Age (years): 23; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-08-29 (19)/ 2020-09-04 (25)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642257; Age (years): 56; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ COVID-19/ COVID-19 POSITIVE	2020-09-25 (7)/ Ongoing	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3652039; Age (years): 33; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 (SARS-COV-2 CONFIRMED 10/27/2020)	2020-10-25 (27)/ 2020-11-03 (36)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672097; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-19 (7)/ 2020-08-23 (11)	Yes/ No/ Yes	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-09-07 (26)/ 2020-10-13 (62)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672151; Age (years): 25; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH LOWER EXTREMITIES	2020-08-18 12:15 (1)/ 2020-08-26 (10)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672187; Age (years): 72; Sex: M; Race: WHITE							
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BLOOD PRESSURE	2020-09-21 (34)/ Ongoing	Yes/ No/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3672278; Age (years): 78; Sex: M; Race: WHITE							
Nervous system disorders/ Speech disorder/ SPEECH DEFICIT	2020-09-10 (11)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-09-10/ 2020-09-11)/4	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Nervous system disorders/ Ischaemic stroke/ ISCHEMIC STROKE (FRONTAL LOBE)	2020-09-10 (11)/ 2020-09-11 (12)	Yes/ Yes/ No	4	Yes/3 (2020-09-10/ 2020-09-11)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: AE OF SPEECH DEFICIT

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672333; Age (years): 19; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (URI)	2020-09-24 (30)/ 2020-09-30 (36)	Yes/ No/ No	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672407; Age (years): 41; Sex: F; Race: WHITE							
Cardiac disorders/ Arrhythmia/ ARRHYTHMIA	2020-09-07 (5)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3682040; Age (years): 48; Sex: M; Race: OTHER: I DON'T KNOW HOW TO ANSWER							
Infections and infestations/ Varicella zoster virus infection/ EXACERBATION OF VARICELLA ZOSTER	2020-09-01 10:55 (1)/ 2020-10-03 (33)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732207; Age (years): 30; Sex: M; Race: ASIAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-09-15 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	UNKNOWN

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742253; Age (years): 44; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-20 (17)/ 2020-09-29 (26)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742395; Age (years): 61; Sex: M; Race: OTHER: (b) (6)							
Vascular disorders/ Deep vein thrombosis/ DEEP VEIN THROMBOSIS	2020-09-25 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742477; Age (years): 49; Sex: F; Race: NOT REPORTED							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-14 (14)/ 2020-10-31 (31)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752366; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-04 (3)/ 2020-09-16 (15)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772051; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Incarcerated hernia/ ACUTE INCARCERATED VENTRAL HERNIA	2020-09-04 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-05/ 2020-09-14)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3782073; Age (years): 56; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Angioedema/ ANGIODEMA	2020-08-28 (5)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812174; Age (years): 18; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-08-14 (1)/ 2020-09-26 (44)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812197; Age (years): 38; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-24 (8)/ 2020-09-26 (41)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822006; Age (years): 51; Sex: F; Race: WHITE							
Eye disorders/ Eye swelling/ SWELLING UNDER EYE, BILATERAL	2020-08-09 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862050; Age (years): 50; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-29 (6)/ 2020-09-11 (19)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862098; Age (years): 45; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ NEW HTN DIAGNOSIS	2020-09-29 (30)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3872138; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-27 (17)/ 2020-09-08 (29)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872138; Age (years): 73; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-08-31 (21)/ 2020-08-31 (21)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Retching/ DRY HEAVES	2020-08-31 (21)/ 2020-08-31 (21)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3902019; Age (years): 61; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON BUTTOCKS AND BILATERAL AXILLA	2020-09-05 (4)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3902064; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-15 (6)/ 2020-09-25 (16)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912241; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM, LLL	2020-11-03 (23)/ 2020-11-09 (29)	Yes/ Yes/ No	4	Yes/3 (2020-11-04/ 2020-11-05)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3922067; Age (years): 77; Sex: F; Race: WHITE							
Psychiatric disorders/ Confusional state/ CONFUSION	2020-09-07 (7)/ 2020-09-09 (9)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-09)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3932147; Age (years): 84; Sex: F; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ WORSENING OF CONGESTIVE HEART FAILURE	2020-10-05 (20)/ 2020-10-11 (26)	Yes/ Yes/ No	4	Yes/3 (2020-10-05/ 2020-10-11)/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932147; Age (years): 84; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ EXACERBATED COPD CAUSED BY WORSENING CONGESTIVE HEART FAILURE	2020-10-05 (20)/ 2020-11-05 (51)	Yes/ Yes/ No	4	Yes/3 (2020-10-05/ 2020-10-11)/6	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3942044; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 (24)/ 2020-10-14 (43)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-25 (24)/ 2020-10-14 (43)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3942079; Age (years): 42; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-09-22 (15)/ 2020-10-16 (39)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3952033; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-10-06 (35)/ 2020-10-25 (54)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952116; Age (years): 75; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-22 (35)/ 2020-10-23 (36)	Yes/ No/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Investigations/ Blood pressure increased/ GRADE 3 BLOOD PRESSURE [INCREASE FROM BASELINE]	2020-10-23 (36)/ 2020-10-23 (36)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.11
Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022012; Age (years): 35; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-07-27 08:00 (1)/ 2020-09-15 (51)	No/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022021; Age (years): 65; Sex: F; Race: WHITE							
Vascular disorders/ Orthostatic hypotension/ ORTHOSTATIC HYOTENSION	2020-09-14 (48)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022031; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Pneumonia/ PNUEMONIA	2020-08-10 (15)/ 2020-08-19 (24)	Yes/ Yes/ No	4	Yes/3 (2020-08-10/ 2020-08-19)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Overdose/ OVERDOSE OF KLONOPIN	2020-08-10 (15)/ 2020-08-19 (24)	Yes/ Yes/ No	4	Yes/3 (2020-08-10/ 2020-08-19)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022031; Age (years): 66; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ LUNG FAILURE	2020-08-10 (15)/ 2020-08-19 (24)	Yes/ Yes/ No	4	Yes/3 (2020-08-10/ 2020-08-19)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022208; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE	2020-09-10 (22)/ 2020-09-14 (26)	Yes/ Yes/ No	4	Yes/3 (2020-09-10/ 2020-09-14)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: DUE TO CONGESTIVE HEART FAILURE IS A NEW DIAGNOSIS.
Subject ID: US3032305; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-09-08 (19)/ 2020-09-08 (19)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042032; Age (years): 81; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ EXACERBATION OF CHRONIC DYSPNEA	2020-08-27 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082051; Age (years): 66; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Pancreatitis acute/ ACUTE PANCREATITIS	2020-08-26 (9)/ 2020-09-30 (44)	Yes/ Yes/ No	4	Yes/3 (2020-08-26/ 2020-09-30)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3122010; Age (years): 62; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Lung cancer metastatic/ RECURRENCE OF THROAT CANCER WITH METASTASES TO LUNGS	2020-08-12 (17)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162078; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-14 (8)/ 2020-09-03 (28)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172265; Age (years): 34; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ SKIN RASH (CONSISTENT WITH HIVES) (ARMS, LEGS, CHEST, AND BACK)	2020-08-22 23:00 (2)/ 2020-08-25 05:00 (4)	Yes/ No/ No	1	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172360; Age (years): 54; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Psoriasis/ PSORIASIS FLARE	2020-09-20 (25)/ 2020-11-17 (83)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212182; Age (years): 20; Sex: F; Race: NOT REPORTED							
Pregnancy, puerperium and perinatal conditions/ Morning sickness/ MORNING SICKNESS	2020-09-13 (31)/ 2020-10-26 (74)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222061; Age (years): 71; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Breast mass/ MASS ON RIGHT BREAST POSSITIVE FOR CANCER	2020-09-04 (26)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3232021; Age (years): 47; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING UPPER EXTREMITIES ARTHRALGIA	2020-08-25 (16)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242288; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-09 (7)/ 2020-09-23 (21)	Yes/ No/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242370; Age (years): 28; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Schizoaffective disorder/ WORSENING OF SCHIZOAFFECTIVE DISORDER	2020-09-29 (7)/ 2020-10-03 (11)	Yes/ Yes/ No	3	Yes/2/3 (2020-09-29/ 2020-10-03)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252075; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-08-13 (7)/ 2020-08-20 (14)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292241; Age (years): 67; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ OCCIPITAL HEADACHE	2020-08-20 (1)/ 2020-09-30 (42)	Yes/ No/ Yes	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292412; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-09-25 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312197; Age (years): 69; Sex: M; Race: WHITE							
Nervous system disorders/ Cervical radiculopathy/ EXACERBATION OF LEFT CERVICAL RADICULOPATHY	2020-09-06 (18)/ 2020-10-09 (51)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312637; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Coronary artery disease/ EXACERBATION OF CORONARY ARTERY DISEASE	2020-10-15 (35)/ 2020-10-16 (36)	Yes/ Yes/ No	2	Yes/3 (2020-10-15/ 2020-10-16)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3332089; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-09-18 21:46 (2)/ 2020-10-09 08:00 (22)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342239; Age (years): 30; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Head injury/ HEAD TRAUMA	2020-10-13 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ R	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362023; Age (years): 55; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Swollen tongue/ TONGUE SWELLING - POST INJECTION ALLERGIC REACTION	2020-08-03 16:20 (1)/ 2020-08-03 18:20 (1)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362124; Age (years): 20; Sex: M; Race: UNKNOWN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-08-18 (6)/ 2020-09-18 (37)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362244; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF LEFT HIP PAIN/ARTHRITIS	2020-09-08 (16)/ 2020-11-11 (80)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382284; Age (years): 45; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Gastric cancer/ GASTRIC CANCER	2020-10-29 (44)/ Ongoing	Yes/ Yes/ No	3	Yes/2/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3392149; Age (years): 30; Sex: M; Race: WHITE							
Infections and infestations/ Hepatitis A/ HEPATITIS A	2020-09-24 (23)/ 2020-09-25 (24)	Yes/ Yes/ No	3	Yes/3 (2020-09-24/ 2020-09-25)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3402300; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Herpes simplex/ HERPES SIMPLEX	2020-08-13 (6)/ Ongoing	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3412129; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-12 (8)/ 2020-09-13 (40)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432334; Age (years): 29; Sex: M; Race: WHITE							
Infections and infestations/ Asymptomatic COVID-19/ SARS-COV-2 INFECTION (ASYMPTOMATIC)	2020-09-16 (20)/ 2020-09-26 (30)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482064; Age (years): 71; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash macular/ NON-URTICARIAL MACULAR RASH WITH BLANCHING ERYTHEMA ON LEFT DELTOID	2020-08-25 (9)/ 2020-09-04 (19)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482284; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-28 (13)/ 2020-10-31 (16)	Yes/ Yes/ No	4	Yes/2/3 (2020-10-29/ 2020-10-31)/4	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SHORTNESS OF BREATH & IMPAIRED CARDIAC FUNCTION (CHF)

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492237; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-09-22 14:00 (1)/ 2020-10-09 (18)	No/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522664; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RIGHT DELTOID MACULAR, NON-URTICARIAL REDNESS AT INJECTION SITE 120MM BY 86MM OBLONG	2020-09-23 (13)/ 2020-09-25 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532279; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-05 (26)/ 2020-10-21 (42)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542332; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Seizure/ EXACERBATION OF SEIZURE DISORDER	2020-11-07 (30)/ 2020-11-08 (31)	Yes/ Yes/ No	3	Yes/3 (2020-11-07/ 2020-11-08)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552035; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-09-04 (22)/ 2020-09-21 (39)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552371; Age (years): 56; Sex: F; Race: WHITE							
Investigations/ Hepatic enzyme increased/ ELEVATED LIVER ENZYMES	2020-09-16 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3552497; Age (years): 22; Sex: F; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash/ RASH TO LEFT ARM	2020-10-03 (8)/ 2020-10-06 (11)	Yes/ No/ No	1	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642268; Age (years): 38; Sex: M; Race: WHITE							
Nervous system disorders/ Neuropathy peripheral/ NEUROPATHY	2020-09-21 (1)/ 2020-11-04 (45)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652038; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-25 (31)/ 2020-11-06 (43)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672092; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (L)	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672092; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE (L)	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672163; Age (years): 56; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ RIGHT ARM ERYTHEMA (URTICARIAL)	2020-08-26 (9)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Induration/ RIGHT ARM INDURATION	2020-08-26 (9)/ 2020-09-02 (16)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672251; Age (years): 42; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE	2020-08-28 (8)/ 2020-08-30 (10)	Yes/ No/ Yes	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3712171; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID19	2020-09-30 (6)/ 2020-10-05 (11)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732262; Age (years): 37; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-09-06 (5)/ 2020-09-19 (18)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732311; Age (years): 32; Sex: F; Race: WHITE							
Product issues/ Device dislocation/ DISPLACED LEFT BREAST SILICONE IMPLANT	2020-09-29 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742169; Age (years): 57; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Rheumatoid arthritis/ RHEUMATOID ARTHRITIS	2020-08-31 23:00 (1)/ Ongoing	Yes/ Yes/ No	2	Yes/6	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3762177; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS, LEFT ARM NON-URTICARIAL	2020-09-03 00:00 (1)/ Ongoing	No/ No/ Yes	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-04 00:00 (1)/ Ongoing	Yes/ No/ Yes	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762177; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ INTERMITTENT BODY ACHES	2020-09-04 00:00 (1)/ Ongoing	Yes/ No/ No	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Abdominal pain upper/ STOMACH ACHE	2020-09-13 (11)/ Ongoing	Yes/ No/ No	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING
Subject ID: US3842060; Age (years): 57; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Asymptomatic COVID-19/ A-SYMPTOMATIC COVID-19	2020-10-26 (6)/ 2020-10-26 (6)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3862175; Age (years): 51; Sex: F; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash pruritic/ RASH [ERYTHEMATOUS AND PRURITIC] OF VACCINATED ARM	2020-09-13 (3)/ 2020-10-02 (22)	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.11
Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862175; Age (years): 51; Sex: F; Race: ASIAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL AXILLARY LYMPHADENOPATHY	2020-09-17 (7)/ 2020-09-25 (15)	Yes/ No/ Yes	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3862286; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL LIKE ILLNESS	2020-11-01 (17)/ 2020-11-11 (27)	Yes/ No/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872501; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ POSITIVE COVID	2020-09-19 (10)/ 2020-10-24 (45)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3902030; Age (years): 66; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ HIVES	2020-09-05 (3)/ 2020-09-21 (19)	Yes/ Yes/ No	1	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.11
Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3922080; Age (years): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-02 (30)/ Ongoing	Yes/ No/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3942021; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT TRAUMA	2020-09-06 (10)/ 2020-10-01 (35)	Yes/ No/ No	3	Yes/3 (2020-09-06/ 2020-09-22)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3942121; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-20 (27)/ 2020-10-30 (37)	Yes/ No/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3952104; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Hip fracture/ HIP FRACTURE	2020-10-05 (19)/ 2020-10-08 (22)	Yes/ Yes/ No	3	Yes/3 (2020-10-07/ 2020-10-12)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.11
Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3972224; Age (years): 27; Sex: M; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Urticaria/ HIVES ON ARM AND BACK	2020-10-14 (3)/ 2020-10-19 (8)	Yes/ No/ No	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3982158; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Idiopathic intracranial hypertension/ WORSENING PSEUDOTUMOR CEREBRI	2020-09-14 (4)/ Ongoing	Yes/ No/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.11
Unsolicited Adverse Events Leading to Discontinuation from Study Vaccine
Safety Set

TEAE = Treatment-Emergent Adverse Event; MAAE = Medically-Attended Adverse Event; AR = Adverse Reaction; SAE = Serious Adverse Event; IP = Investigational Product; SP = Study Procedure.
Relative day is defined as days from the most recent injection date.
MedDRA version 23.0.
[1] Sev. = Severity, 1 = Grade 1/Mild, 2 = Grade 2/Moderate, 3 = Grade 3/Severe, 4 = Grade 4.
[2] 1 = Death, 2 = Life threatening, 3 = Requires inpatient or prolongation of existing Hospitalization (Hospital Admission Date/ Hospital Discharge Date), 4 = Persistent or significant disability or incapacity, 5 = Congenital anomaly or birth defect, 6 = Other medically important event.
[3] R = Related, NR = Not Related, NA = Not Applicable.

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002004; Age (years): 38; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-10 (48)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002031; Age (years): 25; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID-19	2020-07-28 22:00 (1)/ 2020-08-14 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-09 (44)/ 2020-09-12 (47)	Yes/ Yes/ No	2	Yes/3 (2020-09-09/ 2020-09-12)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3002037; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID19	2020-11-01 (68)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002046; Age (years): 60; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Hip fracture/ LEFT BROKEN HIP	2020-08-12 (15)/ 2020-08-14 (17)	Yes/ Yes/ No	3	Yes/3 (2020-08-12/)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3002051; Age (years): 94; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-25 (28)/ 2020-09-25 (59)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002076; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-12 (77)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002079; Age (years): 22; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-29 (33)/ 2020-10-04 (38)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002079; Age (years): 22; Sex: M; Race: WHITE							
Hepatobiliary disorders/ Hepatic steatosis/ FATTY LIVER	2020-10-04 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002097; Age (years): 41; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ POSITIVE COVID-19	2020-09-21 (21)/ 2020-10-05 (35)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Livedo reticularis/ LIVEDO RETICULARIS	2020-09-26 (26)/ 2020-09-26 (26)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3002106; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19 ILLNESS	2020-10-05 08:00 (32)/ 2020-11-10 (69)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002126; Age (years): 35; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ LEFT SHOULDER INJURY	2020-09-30 (27)/ 2020-09-30 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002162; Age (years): 35; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-09-11 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002168; Age (years): 32; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Obesity/ WORSENING OF OBESITY	2020-09-15 09:00 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002169; Age (years): 48; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-24 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002216; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Angioedema/ ACE INHIBITOR INDUCED ANGIOEDEMA	2020-09-11 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Foot fracture/ RIGHT FOOT FRACTURE	2020-10-03 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002222; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ ACUTE LEFT EAR INFECTION	2020-09-28 (29)/ 2020-10-03 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002231; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Muscle strain/ LEFT SHOULDER MUSCLE STRAIN	2020-09-20 (19)/ 2020-09-30 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002236; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ POSITIVE COVID-19	2020-11-13 (45)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002240; Age (years): 42; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-24 (22)/ 2020-09-27 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002251; Age (years): 48; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ NEPHROLITHIASIS	2020-09-19 (16)/ 2020-09-22 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002299; Age (years): 60; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-09-29 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002324; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-09-27 (4)/ 2020-09-27 (4)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002353; Age (years): 24; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ulna fracture/ FRACTURE RIGHT ULNA	2020-10-26 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3002356; Age (years): 30; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION	2020-10-09 (1)/ 2020-10-20 (12)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Contusion/ LEFT NEE CONTUSION	2020-10-09 (1)/ 2020-10-20 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012005; Age (years): 67; Sex: M; Race: WHITE							
Immune system disorders/ Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2020-08-12 (17)/ 2020-08-17 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012008; Age (years): 33; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 (33)/ 2020-09-29 (37)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Wound/ PUNCTURE WOUND IN LEFT FOOT FROM NAIL	2020-10-27 (65)/ 2020-10-27 (65)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012028; Age (years): 71; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL CANCER RIGHT ELBOW	2020-09-15 (21)/ 2020-09-15 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3012040; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Candida infection/ THRUSH	2020-11-02 (67)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012043; Age (years): 50; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Scratch/ RIGHT CALF SCRATCHED BY METAL CONSTRUCTION WIRE	2020-08-23 (24)/ 2020-09-25 (57)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012057; Age (years): 50; Sex: M; Race: ASIAN							
Gastrointestinal disorders/ Toothache/ TOOTH PAIN, LEFT UPPER MOLAR	2020-09-08 (5)/ 2020-10-01 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Toothache/ WORSENING OF TOOTH PAIN, LEFT UPPER MOLAR	2020-10-01 (28)/ 2020-10-01 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Root canal infection/ ORAL INFECTION, DUE TO PARTIAL ROOT CANAL	2020-10-01 (28)/ 2020-10-18 (45)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012057; Age (years): 50; Sex: M; Race: ASIAN							
Injury, poisoning and procedural complications/ Procedural pain/ TOOTH PAIN, LEFT UPPER MOLAR, DUE TO ROOT CANAL	2020-10-20 (47)/ 2020-10-29 (56)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3012079; Age (years): 63; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Cystocele/ WORSENING OF CYSTOCELE	2020-08-27 (21)/ 2020-10-22 (77)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural pain/ POST OP HYSTERECTOMY PAIN	2020-10-22 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012082; Age (years): 60; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS RIGHT KNEE	2020-08-18 (12)/ 2020-09-28 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Bursitis/ BURSITIS	2020-09-23 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012102; Age (years): 67; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ WORSENING OF HYPERCHOLESTEROLEMIA	2020-09-25 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012113; Age (years): 59; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Cyst/ CYST IN LEFT KNEE	2020-10-10 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Hypercholesterolaemia/ WORSENING OF HYPERCHOLESTEROLEMIA	2020-10-26 (48)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-26 (48)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012115; Age (years): 56; Sex: M; Race: WHITE							
Infections and infestations/ Gonorrhoea/ POSSIBLE GONORRHEA (NEGATIVE RESULT)	2020-09-02 (23)/ 2020-09-09 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012138; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS FLARE	2020-09-18 (8)/ 2020-09-21 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012154; Age (years): 32; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-14 (4)/ 2020-09-28 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012157; Age (years): 60; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING OF RIGHT SHOULDER PAIN	2020-09-02 (17)/ 2020-09-04 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012166; Age (years): 64; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ RIGHT INDEX FINGER LACERATION	2020-09-22 (8)/ 2020-09-22 (8)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012181; Age (years): 60; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ DENTAL CARIES	2020-09-15 (28)/ 2020-11-12 (86)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3012194; Age (years): 65; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-09 (82)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012195; Age (years): 52; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-07 (21)/ 2020-10-07 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Ageusia/ NEW LOSS OF TASTE	2020-10-07 (21)/ 2020-10-10 (24)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012195; Age (years): 52; Sex: M; Race: WHITE							
Nervous system disorders/ Anosmia/ NEW LOSS OF SMELL	2020-10-07 (21)/ 2020-10-10 (24)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-07 (21)/ 2020-10-10 (24)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-07 (21)/ 2020-10-10 (24)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-08 (22)/ 2020-10-11 (25)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012211; Age (years): 43; Sex: F; Race: WHITE							
Investigations/ Blood testosterone decreased/ LOW TESTOSTERONE	2020-10-14 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012212; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Rash papular/ PAPULAR RASH, FACE, NON-URTICARIAL	2020-09-14 (22)/ 2020-09-20 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012239; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-08 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012244; Age (years): 54; Sex: M; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ADHD	2020-10-23 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012254; Age (years): 55; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH - LEFT SIDE OF GLUTEUS	2020-10-30 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012256; Age (years): 42; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ ANKLE SPRAIN RIGHT	2020-11-01 (34)/ 2020-11-22 (55)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012263; Age (years): 50; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Loose tooth/ LOOSE MOLAR	2020-09-15 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Gun shot wound/ GUNSHOT WOUND, RIGHT SHOULDER AND SPINE	2020-11-08 (40)/ Ongoing	Yes/ Yes/ No	4	Yes/2/3 (2020-11-09/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012263; Age (years): 50; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Traumatic fracture/ COMPOUND FRACTURE, T4 AND T3 RIBS, SECONDARY TO GUNSHOT WOUND	2020-11-09 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Anxiety/ POST-TRAUMATIC ANXIETY	2020-11-09 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pneumothorax/ BILATERAL LUNG COLLAPSE	2020-11-09 (41)/ 2020-11-15 (47)	Yes/ Yes/ No	4	Yes/2/3 (2020-11-08/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ RASH, BACK AND BUTTOCKS	2020-11-15 (47)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012297; Age (years): 48; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION, DUE TO HANGOVER	2020-09-19 (6)/ 2020-09-20 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Arrhythmia/ WORSENING OF ARRHYTHMIA, DUE TO HANGOVER	2020-09-19 (6)/ 2020-09-22 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Hangover/ HANGOVER	2020-09-19 (6)/ 2020-09-22 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012312; Age (years): 52; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Nervous system disorders/ Paraesthesia/ TINGLING, RIGHT SIDE OF NECK, SHOULDER	2020-10-13 07:00 (1)/ 2020-10-14 15:00 (2)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012312; Age (years): 52; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-26 (15)/ 2020-10-30 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012318; Age (years): 32; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-19 (5)/ 2020-09-23 (9)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012332; Age (years): 30; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Erectile dysfunction/ ERECTILE DYSFUNCTION	2020-10-20 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022004; Age (years): 62; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod sting/ YELLOW JACKET STING	2020-10-26 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022057; Age (years): 64; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	2020-08-23 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022065; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS/LARYNIGITIS	2020-10-24 (53)/ 2020-10-27 (56)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-24 (53)/ 2020-11-07 (67)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-24 (53)/ 2020-11-09 (69)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022065; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-24 (53)/ 2020-11-09 (69)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Ageusia/ AGEUSIA	2020-10-25 (54)/ 2020-10-27 (56)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-25 (54)/ 2020-11-09 (69)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-25 (54)/ 2020-11-09 (69)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022065; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Acute sinusitis/ ACUTE SINUSITIS	2020-10-26 (55)/ 2020-11-09 (69)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022066; Age (years): 71; Sex: M; Race: WHITE							
Renal and urinary disorders/ Haematuria/ HEMATURIA	2020-08-14 (17)/ 2020-08-18 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Prostatitis/ PROSTATITIS	2020-08-14 (17)/ 2020-08-18 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022071; Age (years): 66; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-18 08:00 (20)/ 2020-08-20 13:00 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022083; Age (years): 66; Sex: F; Race: WHITE							
Surgical and medical procedures/ Carpal tunnel decompression/ CARPAL TUNNEL SURGERY LEFT HAND	2020-09-23 (14)/ 2020-09-23 (14)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022097; Age (years): 38; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-08-26 (27)/ 2020-09-02 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022119; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ LEFT SIDE OF FACE TINGLING	2020-10-13 (20)/ 2020-10-16 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022119; Age (years): 46; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTROINTESTINAL HEMORRHAGE	2020-10-16 (23)/ 2020-10-16 (23)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022123; Age (years): 41; Sex: M; Race: WHITE							
Infections and infestations/ Mastoiditis/ MASTOIDITIS RIGHT	2020-08-10 (5)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022134; Age (years): 42; Sex: F; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT DISORDER	2020-10-14 (37)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022160; Age (years): 62; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-13 (28)/ 2020-09-18 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-13 (28)/ 2020-09-21 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-13 (28)/ 2020-09-21 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-14 (29)/ 2020-09-14 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022160; Age (years): 62; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-14 (29)/ 2020-09-16 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-14 (29)/ 2020-09-18 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ GENERALIZED BODY ACHES	2020-09-14 (29)/ 2020-09-18 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022160; Age (years): 62; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-14 (29)/ 2020-09-18 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-15 (30)/ 2020-09-18 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022184; Age (years): 46; Sex: F; Race: WHITE							
Investigations/ Cardiac murmur/ HEART MURMER	2020-10-19 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN
Subject ID: US3022186; Age (years): 66; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Rib fracture/ FRACTURE RIBS	2020-10-11 (18)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-11/ 2020-10-14)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022186; Age (years): 66; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE	2020-10-11 (18)/ 2020-10-11 (18)	Yes/ Yes/ No	4	Yes/3 (2020-10-11/ 2020-10-14)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-11 (18)/ 2020-10-14 (21)	Yes/ Yes/ No	4	Yes/3 (2020-10-11/ 2020-10-14)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-11 (49)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-11-11 (49)/ 2020-11-13 (51)	Yes/ Yes/ No	4	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022223; Age (years): 45; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS SORE THROAT	2020-11-11 (56)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022229; Age (years): 75; Sex: F; Race: ASIAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-18 (29)/ 2020-09-22 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022233; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-02 (9)/ 2020-10-06 (13)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-10-02 (9)/ 2020-10-21 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022239; Age (years): 21; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT CERVICAL LYMPHADENOPATHY	2020-10-20 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN
Subject ID: US3022241; Age (years): 24; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ TENDINITIS RIGHT WRIST	2020-08-27 (7)/ 2020-09-11 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022243; Age (years): 36; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 (35)/ 2020-09-26 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022243; Age (years): 36; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-24 (35)/ 2020-09-26 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (35)/ 2020-09-26 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-24 (35)/ 2020-09-26 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022255; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ HERPES ZOSTER	2020-10-27 (35)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022278; Age (years): 69; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Epistaxis/ NOSE BLEED	2020-08-28 (8)/ 2020-08-28 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022285; Age (years): 59; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN IN FINGERS AND BILATERAL HANDS	2020-09-14 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-10-28 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022291; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF RIGHT KNEE ARTHRITIS	2020-11-09 (43)/ 2020-11-12 (46)	Yes/ Yes/ No	4	Yes/3 (2020-11-09/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022303; Age (years): 39; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Arthropod bite/ LEFT ANKLE BUG BITE	2020-09-07 (5)/ 2020-09-10 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-12 (15)/ 2020-10-13 (16)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022308; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ LEFT GROIN STRAIN	2020-09-14 (12)/ 2020-10-09 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022310; Age (years): 59; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Stress fracture/ LEFT FOOT STRESS FRACTURE	2020-09-18 (16)/ 2020-10-26 (54)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022311; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Renal and urinary disorders/ Nephrolithiasis/ WORSENING OF NEPHROLITHIASIS	2020-09-24 (17)/ 2020-10-06 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022335; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-11-02 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3032009; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-26 (63)/ 2020-11-05 (73)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032035; Age (years): 55; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myositis/ RIGHT SHOULDER MUSCLE INFLAMMATION	2020-08-25 (28)/ 2020-11-09 (104)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID -19	2020-11-14 (81)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-14 (81)/ 2020-11-14 (81)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032040; Age (years): 34; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-08-28 (3)/ 2020-09-07 (13)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032046; Age (years): 29; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-18 (47)/ 2020-10-22 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-10-18 (47)/ 2020-10-30 (59)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032060; Age (years): 44; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS OF LOWER BACK	2020-10-12 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3032061; Age (years): 31; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-02 (6)/ 2020-09-04 (8)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3032071; Age (years): 47; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-22 00:00 (50)/ 2020-10-31 (60)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032083; Age (years): 45; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Constipation/ WORSENING OF CONSTIPATION	2020-08-30 (27)/ 2020-10-05 (63)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032095; Age (years): 25; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-05 (65)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032098; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS OF RIGHT HALLUX	2020-10-02 (29)/ 2020-10-11 (38)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032108; Age (years): 29; Sex: F; Race: WHITE							
Nervous system disorders/ Tension headache/ TENSION HEADACHE	2020-08-08 (4)/ 2020-08-25 (21)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032110; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-18 (72)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3032123; Age (years): 33; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID -19	2020-11-15 (68)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-17 (70)/ 2020-11-19 (72)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032134; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-15 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032171; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-10 (32)/ 2020-09-24 (46)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED URTICARIA	2020-09-13 (35)/ 2020-09-24 (46)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032172; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-08-31 (22)/ 2020-09-08 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID 19	2020-09-01 (23)/ 2020-09-08 (30)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032188; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABCESS	2020-08-15 (5)/ 2020-08-25 (15)	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3032195; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Cystitis/ CYSTITIS	2020-09-22 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032204; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (57)/ 2020-11-16 (64)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	FATAL
Subject ID: US3032213; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-15 (62)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032221; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID-19	2020-11-16 (63)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3032227; Age (years): 31; Sex: F; Race: WHITE							
Immune system disorders/ Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2020-09-09 (22)/ 2020-09-16 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032244; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ RIGHT LOWER ABSCESS OF TOOTH	2020-10-12 (26)/ 2020-10-19 (33)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3032251; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-14 (27)/ 2020-09-21 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032251; Age (years): 66; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	2020-09-25 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032265; Age (years): 38; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-09-30 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032267; Age (years): 67; Sex: F; Race: WHITE							
Immune system disorders/ Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2020-10-20 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3032277; Age (years): 90; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Duodenal ulcer haemorrhage/ ACUTE DUODENAL ULCER WITH HEMORRHAGE	2020-09-12 (24)/ 2020-09-17 (29)	Yes/ Yes/ No	4	Yes/3 (2020-09-13/ 2020-09-17)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032283; Age (years): 72; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS RIGHT EAR AND CHEEK	2020-09-09 (21)/ 2020-09-30 (42)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032303; Age (years): 58; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ SPRAINED LOWER BACK MUSCLES TRIMMING TREES	2020-10-15 (22)/ 2020-10-18 (25)	Yes/ Yes/ No	1			NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032316; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-16 (22)/ 2020-10-31 (37)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032333; Age (years): 41; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Medical device site inflammation/ INFLAMMATION AROUND BONE SCREWS IN BACK	2020-09-11 (21)/ 2020-09-11 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032344; Age (years): 22; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-03 (33)/ 2020-11-10 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042003; Age (years): 72; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-18 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042011; Age (years): 58; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-08-11 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042011; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-02 (68)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042015; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Hordeolum/ BILATERAL HORDEOLUM	2020-08-08 (11)/ 2020-09-15 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042018; Age (years): 30; Sex: M; Race: MULTIPLE:				(b) (6)			
Infections and infestations/ Tooth infection/ DENTAL INFECTION	2020-08-11 (14)/ 2020-08-18 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042026; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-13 (43)/ 2020-11-09 (70)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042028; Age (years): 37; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-24 (29)/ 2020-11-10 (76)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-10-28 (63)/ 2020-11-04 (70)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042035; Age (years): 61; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-06 (8)/ 2020-08-27 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042043; Age (years): 37; Sex: F; Race: WHITE							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-09-22 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042052; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis bacterial/ BACTERIAL SINUSITIS	2020-09-10 (3)/ 2020-09-30 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042064; Age (years): 21; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ GENERALIZED ACNE	2020-09-21 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042067; Age (years): 41; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-09-11 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042069; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-27 (57)/ 2020-11-07 (68)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042091; Age (years): 43; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	2020-08-22 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042100; Age (years): 48; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-10 (38)/ 2020-11-12 (71)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3042113; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Non-cardiac chest pain/ CHEST PAIN-NON-CARDIAC	2020-09-14 (6)/ 2020-09-21 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Pneumonia/ LEFT LOWER LOBE PNEUMONIA	2020-09-17 (9)/ 2020-09-21 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042114; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-22 (49)/ 2020-11-03 (61)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042115; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-03 (61)/ 2020-11-16 (74)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3042135; Age (years): 38; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-03 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042136; Age (years): 40; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENED ANXIETY	2020-09-28 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042153; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-04 (57)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042173; Age (years): 48; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ BROKEN TOE-LEFT FOOT-3RD TOE IN	2020-09-16 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042175; Age (years): 64; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ MIGRAINE EXACERBATION	2020-10-08 (29)/ 2020-10-08 (29)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042181; Age (years): 69; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-09-04 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042187; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING LEFT SHOULD PAIN	2020-08-20 (8)/ 2020-08-20 (8)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042189; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-12 (3)/ 2020-10-13 (34)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042191; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-08 (23)/ 2020-10-18 (33)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042200; Age (years): 54; Sex: F; Race: WHITE							
Social circumstances/ Menopause/ PREMENOPAUSE	2020-09-22 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042205; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis bacterial/ BACTERIAL SINUSITIS	2020-10-29 (49)/ 2020-11-08 (59)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042209; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-08 (26)/ 2020-10-06 (54)	Yes/ Yes/ No	1	No	NR/ NA	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis bacterial/ ACUTE BACTERIAL SINUSITIS	2020-09-18 (36)/ 2020-09-28 (46)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042210; Age (years): 62; Sex: M; Race: WHITE							
Nervous system disorders/ Arachnoid cyst/ GROWING/WORSENING OF ARACHNOID CYST ON LUMBER SPINE	2020-11-01 (49)/ 2020-11-03 (51)	Yes/ Yes/ No		No		NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042226; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-28 (43)/ 2020-11-14 (60)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042232; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-03 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042244; Age (years): 59; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-02 (48)/ 2020-11-08 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3042252; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-24 (9)/ 2020-10-21 (36)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042253; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-24 (9)/ 2020-10-21 (36)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3042264; Age (years): 68; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ 3 RUPTURED DISCS IN LUMBAR SPINE	2020-10-26 (40)/ Ongoing	Yes/ Yes/ No	1	Yes/3 (2020-10-26/ 2020-10-28)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3042270; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ Oral candidiasis/ ORAL CANDIDIASIS	2020-09-01 (13)/ 2020-10-02 (44)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042295; Age (years): 61; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-09-21 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042309; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-09-18 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3052141; Age (years): 29; Sex: F; Race: MULTIPLE:				(b) (6)			
Infections and infestations/ COVID-19/ COVID POSITIVE	2020-11-19 (67)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3052209; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 POSITIVE	2020-11-17 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/	RECOVERING/ RESOLVING
Subject ID: US3052220; Age (years): 68; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenitis/ LEFT SIDED LYMPHADENITIS	2020-10-01 (15)/ 2020-10-13 (27)	Yes/ Yes/ Yes	1	No			RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3052273; Age (years): 38; Sex: F; Race: WHITE							
Nervous system disorders/ Horner's syndrome/ HORNER'S SYNDROME	2020-09-27 (14)/ 2020-10-09 (26)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3052295; Age (years): 38; Sex: F; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE	2020-09-24 14:08 (2)/ 2020-09-25 10:18 (2)	Yes/ Yes/ No	3	Yes/3 (2020-09-24/ 2020-09-26)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3052374; Age (years): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE, LOWER ABDOMINAL PAIN	2020-10-14 (8)/ 2020-10-14 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/	
Subject ID: US3062001; Age (years): 34; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 (22)/ 2020-09-25 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062001; Age (years): 34; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-22 (25)/ 2020-09-25 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-22 (25)/ 2020-09-25 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-22 (25)/ 2020-09-25 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-22 (25)/ 2020-09-26 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062015; Age (years): 60; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE, RIGHT HAND	2020-08-16 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062018; Age (years): 31; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-28 (32)/ 2020-10-05 (39)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062020; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABSESS TOOTH	2020-09-24 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Viral infection/ VIRAL SYNDORME	2020-10-01 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062022; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-11-17 (81)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062040; Age (years): 54; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-08-04 22:00 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062045; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-17 (18)/ 2020-10-01 (32)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-09-17 (18)/ 2020-10-01 (32)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062099; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-01 (61)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3062100; Age (years): 23; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-11-03 (63)/ 2020-11-09 (69)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3062109; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS, RIGHT ROOT	2020-08-23 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3062131; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID19	2020-11-01 (60)/ 2020-11-16 (75)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062135; Age (years): 55; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES, GENERALIZED	2020-08-12 (7)/ 2020-08-15 (10)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-16 (11)/ 2020-08-23 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-16 (11)/ 2020-08-30 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-17 (12)/ 2020-08-22 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062135; Age (years): 55; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-08-17 (12)/ 2020-08-22 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-17 (12)/ 2020-08-23 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-19 (14)/ 2020-08-21 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3062147; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Cystitis/ BLADDER INFECTION	2020-08-25 (19)/ 2020-09-01 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062155; Age (years): 32; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prolactin-producing pituitary tumour/ PROLACTINOMA	2020-09-16 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062167; Age (years): 56; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-10-16 (39)/ Ongoing	Yes/ Yes/ No	4	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062173; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-27 (53)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062193; Age (years): 19; Sex: F; Race: WHITE							
Infections and infestations/ Influenza/ INFLUENZA A	2020-10-19 (39)/ 2020-10-25 (45)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062198; Age (years): 23; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-25 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062204; Age (years): 18; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISORDER	2020-08-31 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062230; Age (years): 61; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-15 (35)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062241; Age (years): 45; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Wound/ PUNCTURE WOUND LEFT HAND	2020-08-31 (18)/ 2020-09-06 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-22 (39)/ 2020-10-28 (45)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Psychiatric disorders/ Anxiety/ ANXIETY	2020-11-05 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062249; Age (years): 59; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-09-09 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062249; Age (years): 59; Sex: M; Race: WHITE							
Infections and infestations/ Respiratory tract infection viral/ VIRAL RESPIRATORY INFECTION	2020-10-20 (39)/ 2020-10-21 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3062267; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ Nasopharyngitis/ COMMON OLD	2020-09-23 (12)/ 2020-09-29 (18)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062268; Age (years): 46; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-16 (5)/ 2020-09-19 (8)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062273; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Nasopharyngitis/ COMMON COLD	2020-10-04 (23)/ 2020-10-13 (32)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062279; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDORME	2020-10-16 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062305; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-01 (23)/ 2020-10-09 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3062311; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Respiratory tract infection viral/ VIRAL RESPIRATORY INFECTION	2020-10-07 12:00 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082003; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ WORSENING OF SINUSITIS	2020-10-02 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3082004; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media/ OTITIS MEDIA	2020-11-20 (72)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3082012; Age (years): 69; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-12 (3)/ 2020-09-08 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3082012; Age (years): 69; Sex: F; Race: WHITE							
Nervous system disorders/ Restless legs syndrome/ RESTLESS LEG SYNDROME	2020-09-21 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3082021; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-06 (26)/ 2020-09-10 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082038; Age (years): 47; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ BACK SPRAIN	2020-08-22 (6)/ 2020-09-09 (24)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-09-01 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082052; Age (years): 69; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant melanoma/ MELANOMA ON RIGHT CALF	2020-08-21 (4)/ 2020-08-28 (11)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3082066; Age (years): 35; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ BRUISED BIG TOE ON RIGHT FOOT	2020-10-13 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082068; Age (years): 29; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ DEPRESSION	2020-09-18 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3082091; Age (years): 78; Sex: F; Race: WHITE							
Vascular disorders/ Hot flush/ HOT FLASHES	2020-09-10 (18)/ 2020-09-27 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082091; Age (years): 78; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Abnormal loss of weight/ WEIGHT LOSS (UNEXPLAINED)	2020-09-24 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082095; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS [BOTH KNEES]	2020-11-03 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082100; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ Hordeolum/ STYE ON LEFT EYE LID	2020-10-05 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-11-10 (48)/ 2020-11-17 (55)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082118; Age (years): 67; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL-RIGHT FOREARM/UPPER ARM	2020-09-18 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082149; Age (years): 57; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-09-24 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Back injury/ HURT BACK	2020-10-13 (14)/ 2020-10-13 (14)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082176; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Conjunctivitis/ WORSENING OF CONJUNCTIVITIS	2020-09-02 00:00 (1)/ 2020-09-09 00:00 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082179; Age (years): 54; Sex: F; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2020-10-31 (31)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082193; Age (years): 32; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ DENTAL ABSCESS	2020-09-18 (16)/ 2020-10-15 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082198; Age (years): 58; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ PASSED OUT R/T VASOVAGAL SYNCOPE	2020-09-07 (4)/ 2020-09-07 (4)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082203; Age (years): 66; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL CARCINOMA [LEFT FOREARM]	2020-10-04 (27)/ 2020-10-23 (46)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082237; Age (years): 72; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Periarthritis/ "FROZEN" SHOULDER	2020-10-07 (24)/ 2020-10-29 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082248; Age (years): 69; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-16 10:15 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082269; Age (years): 75; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Cardiac disorders/ Atrial fibrillation/ NEW ONSET ATRIAL FIBRILLATION	2020-10-02 (12)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Gastric perforation/ INTRA-ABDOMINAL PERFORATION	2020-10-02 (12)/ 2020-10-03 (13)	Yes/ Yes/ No	4	Yes/1/3 (2020-10-02/)/4/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	FATAL
Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	2020-10-02 (12)/ 2020-10-03 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3092006; Age (years): 61; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression/ DEPRESSION	2020-10-02 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092019; Age (years): 35; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-10 (70)/ Ongoing	Yes/ Yes/ No	1	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3092034; Age (years): 53; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-26 (32)/ 2020-11-14 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3092043; Age (years): 69; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA EXACERBATION	2020-10-02 (30)/ 2020-11-10 (69)	Yes/ Yes/ No	2	Yes/3 (2020-10-28/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092043; Age (years): 69; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION	2020-10-02 (30)/ 2020-11-10 (69)	Yes/ Yes/ No	2	Yes/3 (2020-10-28/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3092047; Age (years): 47; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-08-10 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3092050; Age (years): 26; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant melanoma/ RIGHT LEG MELANOMA & C2	2020-08-19 (13)/ 2020-08-29 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092118; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-08-15 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3092120; Age (years): 70; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-08-17 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3092142; Age (years): 48; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ankle fracture/ BROKEN ANKLE	2020-10-10 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3092160; Age (years): 22; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ WORSENING MILD INTERMITTENT ACNE	2020-11-14 (53)/	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092168; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Toothache/ BILATERAL TEETH (WISDOM) PAIN	2020-11-13 (50)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3092171; Age (years): 61; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-11-13 (53)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-11-13 (53)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-13 (53)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092245; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT	2020-11-21 (54)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-21/)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3092246; Age (years): 27; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-09-29 (1)/ 2020-10-16 (18)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3092303; Age (years): 67; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH- FACE	2020-10-20 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ RASH-THIGHS	2020-10-20 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102052; Age (years): 65; Sex: M; Race: WHITE							
Cardiac disorders/ Arrhythmia/ ARRHYTHMIA	2020-10-19 (56)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3102146; Age (years): 25; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-04 (31)/ 2020-10-11 (38)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3102191; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABCESS	2020-09-25 (17)/ 2020-10-05 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3102283; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (48)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-14/ 2020-11-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3102283; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Asthenia/ WEAKNESS	2020-11-09 (48)/ 2020-11-14 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-09 (48)/ 2020-11-17 (56)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ BODY ACHES - ALL JOINTS	2020-11-09 (48)/ 2020-11-17 (56)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-12 (51)/ 2020-11-15 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3102283; Age (years): 57; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-13 (52)/ 2020-11-14 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-11-14 (53)/ 2020-11-14 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ TINGLING IN BILATERAL HANDS AND BILATERAL FEET	2020-11-14 (53)/ 2020-11-14 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	2020-11-14 (53)/ 2020-11-14 (53)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3102283; Age (years): 57; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION SECONDARY TO DIARRHEA	2020-11-14 (53)/ 2020-11-17 (56)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Electrolyte imbalance/ ELECTROLYTE ABNORMALITY SECONDARY TO DIARRHEA	2020-11-14 (53)/ 2020-11-17 (56)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Sinus bradycardia/ SINUS BRADYCARDIA	2020-11-14 (53)/ 2020-11-18 (57)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypotension/ LOW BLOOD PRESSURE	2020-11-14 (53)/ 2020-11-18 (57)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3102283; Age (years): 57; Sex: F; Race: WHITE							
Cardiac disorders/ Sinus arrest/ SINUS PAUSE	2020-11-15 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3102285; Age (years): 49; Sex: F; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-10 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3102317; Age (years): 77; Sex: M; Race: WHITE							
Vascular disorders/ Aortic aneurysm/ AORTIC ANEURYSM	2020-10-16 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3102323; Age (years): 44; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-09-07 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Stress/ STRESS	2020-09-07 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102323; Age (years): 44; Sex: M; Race: WHITE							
Psychiatric disorders/ Insomnia/ INSOMNIA	2020-09-22 (19)/ 2020-09-30 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3102344; Age (years): 28; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ ACID REFLUX	2020-09-24 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-24 (14)/ 2020-09-28 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-11 (31)/ 2020-10-11 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102344; Age (years): 28; Sex: M; Race: WHITE							
Renal and urinary disorders/ Haematuria/ MICRO HEMATURIA	2020-10-13 (33)/ 2020-10-15 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112049; Age (years): 22; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 DIAGNOSIS	2020-11-02 (67)/ 2020-11-10 (75)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112062; Age (years): 31; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-21 (52)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3112130; Age (years): 36; Sex: F; Race: ASIAN							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Benign breast neoplasm/ BENIGN RIGHT BREAST NODULE	2020-10-01 (29)/ 2020-10-10 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112145; Age (years): 42; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-11-15 (73)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	UNKNOWN
Nervous system disorders/ Headache/ HEADACHE	2020-11-15 (73)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Nervous system disorders/ Paraesthesia/ RIGHT UPPER EXTREMITY TINGLING	2020-11-15 (73)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	UNKNOWN

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112150; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Wrist fracture/ FRACTURED LEFT WRIST	2020-09-27 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3112151; Age (years): 23; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Ingrown hair/ LEFT UNDERARM INGROWN HAIR	2020-10-01 (28)/ 2020-10-06 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT HYPERACTIVITY DISORDER	2020-10-16 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112159; Age (years): 61; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-11 (65)/ 2020-11-12 (66)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112162; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-08-27 (18)/ 2020-08-29 (20)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112164; Age (years): 76; Sex: M; Race: WHITE							
Cardiac disorders/ Coronary artery disease/ SEVERE CORONARY ARTERY DISEASE	2020-09-18 (11)/ 2020-09-24 (17)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-18/ 2020-09-24)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112164; Age (years): 76; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	2020-10-02 (25)/ 2020-10-02 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-02/ 2020-10-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3112173; Age (years): 77; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ PAIN SECONDARY TO SPINAL FUSION	2020-08-25 (16)/ 2020-09-21 (43)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Impaired healing/ POOR WOUND HEALING	2020-09-17 (8)/ 2020-10-03 (24)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112179; Age (years): 32; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ URI	2020-08-21 (12)/ 2020-08-30 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112192; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ LEFT KNEE CONTUSION SECONDARY TO MECHANICAL FALL	2020-09-01 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Contusion/ LEFT SHOULDER CONTUSION SECONDARY TO MECHANICAL FALL	2020-09-01 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112192; Age (years): 67; Sex: F; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ PAROXYSMAL ATRIAL FIBRILLATION	2020-10-17 (37)/ 2020-10-20 (40)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112205; Age (years): 65; Sex: M; Race: WHITE							
Endocrine disorders/ Hypothyroidism/ WORSENING OF HYPOTHYROIDISM	2020-09-01 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112223; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP-PHARYNGITIS	2020-09-01 (20)/ 2020-09-14 (33)	Yes/ Yes/ No	3	Yes/3 (2020-09-02/ 2020-09-03)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112260; Age (years): 57; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle rupture/ RIGHT UPPER ARM MUSCLE TEAR	2020-09-19 (10)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112265; Age (years): 52; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ L SHOULDER TORN ROTATOR CUFF PAIN	2020-09-17 (3)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ L SHOULDER CALCIFIC TENDONITIS	2020-11-01 (48)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	UNKNOWN
Subject ID: US3112266; Age (years): 28; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 DIAGNOSIS	2020-09-06 (24)/ 2020-09-26 (44)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112267; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 DIAGNOSIS	2020-09-06 (24)/ 2020-09-17 (35)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112289; Age (years): 31; Sex: F; Race: ASIAN							
Injury, poisoning and procedural complications/ Procedural haemorrhage/ BLEEDING FROM SURGICAL SITE	2020-10-05 (21)/ 2020-10-06 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112316; Age (years): 50; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-09-06 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112365; Age (years): 69; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Thoracic vertebral fracture/ T12 FRACTURE	2020-10-28 (38)/ 2020-11-02 (43)	Yes/ Yes/ No	4	Yes/3 (2020-11-02/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112368; Age (years): 59; Sex: F; Race: ASIAN							
Vascular disorders/ Hypertension/ HYPERTENSION DIAGNOSIS	2020-09-08 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3112402; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Candida infection/ THRUSH	2020-10-24 (31)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112450; Age (years): 56; Sex: F; Race: ASIAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-10 (9)/ 2020-10-13 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122032; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 - SYMPTOMATIC	2020-11-16 (84)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122059; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19 SYMPTOMATIC	2020-11-15 (81)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3122116; Age (years): 21; Sex: F; Race: WHITE							
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-10-01 (36)/ 2020-10-04 (39)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122142; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-13 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3132006; Age (years): 51; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Investigations/ Heart rate increased/ INCREASED HEART RATE	2020-08-27 (21)/ 2020-08-27 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3132012; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Candida infection/ THRUSH	2020-09-18 (9)/ 2020-09-22 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Sialoadenitis/ RIGHT SIDE SALIVARY GLAND INFECTION	2020-11-06 (58)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3132017; Age (years): 69; Sex: M; Race: WHITE							
Investigations/ Blood cholesterol increased/ WORSENING HIGH CHOLESTEROL	2020-11-13 (57)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3132035; Age (years): 33; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Tympanic membrane perforation/ RIGHT EAR DRUM PERFORATION	2020-09-02 22:00 (2)/ 2020-09-17 10:00 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3132056; Age (years): 30; Sex: M; Race: WHITE							
Infections and infestations/ Gingivitis/ GINGIVITIS	2020-09-29 (14)/ 2020-10-15 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3132154; Age (years): 54; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-11-19 08:00 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3142100; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-21 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3142252; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-07 (47)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3142255; Age (years): 23; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-13 (52)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152005; Age (years): 44; Sex: F; Race: WHITE							
Investigations/ Lipase increased/ ELEVATED LIPASE	2020-07-30 (4)/ 2020-08-11 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Otitis media/ OTITIS MEDIA	2020-09-10 (18)/ 2020-09-20 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152005; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-09-10 (18)/ 2020-09-20 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152020; Age (years): 43; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-07-28 18:44 (1)/ 2020-07-29 15:00 (1)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Glycosylated haemoglobin increased/ ELEVATED HEMOGLOBIN A1C LEVELS	2020-11-13 (81)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152025; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-14 (17)/ 2020-08-27 (30)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: COUGH

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152028; Age (years): 56; Sex: F; Race: WHITE							
Immune system disorders/ Allergy to plants/ ALLERGIC REACTION POISON IVY	2020-07-31 (3)/ 2020-08-05 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152033; Age (years): 19; Sex: M; Race: ASIAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-12 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152034; Age (years): 22; Sex: F; Race: ASIAN							
Blood and lymphatic system disorders/ Iron deficiency anaemia/ IRON DEFICIENCY ANEMIA	2020-10-01 (37)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152035; Age (years): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-19 (50)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152042; Age (years): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-05 (35)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152044; Age (years): 69; Sex: F; Race: WHITE							
Eye disorders/ Dacryostenosis acquired/ RIGHT EYE TEAR DUCT OBSTRUCTION	2020-08-13 (15)/ 2020-09-24 (57)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Eye disorders/ Dacryostenosis acquired/ L EYE TEAR DUCT OBSTRUCTION	2020-08-13 (15)/ 2020-09-28 (61)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3152049; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-09-06 (11)/ 2020-09-14 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152061; Age (years): 24; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-09-30 (30)/ 2020-10-10 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152072; Age (years): 55; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-02 08:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152085; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media/ OTITIS MEDIA	2020-11-04 (58)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152096; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-25 (21)/ 2020-09-02 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152111; Age (years): 40; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-14 (34)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152118; Age (years): 24; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ POST OPERATIVE PAIN	2020-09-11 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152139; Age (years): 49; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-10-09 (25)/ 2020-10-09 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-09 (25)/ 2020-10-10 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152139; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-10-09 (25)/ 2020-10-13 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152145; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ Hordeolum/ STYE RIGHT EYE	2020-10-28 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152190; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Arthropod bite/ TICK BITE, LEFT GROIN AREA	2020-08-18 (5)/ 2020-08-18 (5)	Yes/ Yes/ No	1	No	NA/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152194; Age (years): 54; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ BILATERAL PULMONARY EMBOLISM WITH PULMONARY INFARCTS	2020-09-21 (11)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152207; Age (years): 57; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-09-01 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Tooth abscess/ ABCESS, TOOTH	2020-10-03 (20)/ 2020-10-03 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152210; Age (years): 45; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH	2020-08-28 (15)/ 2020-09-03 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152211; Age (years): 25; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-12 (58)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152223; Age (years): 44; Sex: M; Race: ASIAN							
Gastrointestinal disorders/ Dysphagia/ DYSPHAGIA	2020-10-19 (32)/ 2020-11-02 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3152245; Age (years): 51; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING ANXIETY	2020-10-08 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152259; Age (years): 42; Sex: F; Race: WHITE							
Psychiatric disorders/ Bipolar disorder/ WORSENING OF BIPOLAR DISORDER	2020-08-29 (15)/ 2020-09-07 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3152259; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ CONFIRMED COVID-19 INFECTION	2020-10-07 (23)/ 2020-10-26 (42)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Stress fracture/ STRESS FRACTURE RIGHT FOOT	2020-10-12 (28)/ 2020-11-17 (64)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152264; Age (years): 58; Sex: F; Race: WHITE							
Eye disorders/ Vitreous detachment/ RIGHT POSTERIOR VITREOUS DETACHMENT	2020-09-22 (8)/ Ongoing	Yes/ Yes/ No	1	No	NA/ NA	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152297; Age (years): 23; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING OF ANXIETY	2020-10-14 (29)/ 2020-10-19 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152301; Age (years): 41; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Cerumen impaction/ LEFT EAR CERUMEN IMPACTION	2020-10-02 (16)/ 2020-10-06 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3152308; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-31 (12)/ 2020-09-04 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152349; Age (years): 59; Sex: M; Race: WHITE							
Nervous system disorders/ Sciatica/ SCIATICA LEFT-SIDED EXACERBATION	2020-08-23 (3)/ 2020-08-26 (6)	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152356; Age (years): 60; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-20 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152366; Age (years): 60; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA LEFT LEG (BENIGN)	2020-08-31 (11)/ 2020-10-06 (47)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Contusion/ RIGHT CHEST CONTUSION	2020-09-14 (25)/ 2020-09-19 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152374; Age (years): 54; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING OR RIGHT SHOULD PAIN	2020-11-16 (53)/ 2020-11-16 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152378; Age (years): 44; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin lesion/ LEFT KNEE SKIN LESION	2020-09-13 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS - POISON IVY	2020-09-16 (26)/ 2020-10-10 (50)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152386; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ WORSENING OF MIGRAINES	2020-08-30 (6)/ 2020-09-02 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-09-26 00:00 (1)/ 2020-09-29 00:00 (4)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152386; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-27 (33)/ 2020-11-01 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-18 (55)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Vulvovaginal candidiasis/ VAGINAL CANDIDIASIS	2020-11-18 (55)/ 2020-11-21 (58)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152389; Age (years): 50; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-14 (19)/ 2020-09-18 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152394; Age (years): 38; Sex: F; Race: MULTIPLE:				(b) (6)			
Skin and subcutaneous tissue disorders/ Rash/ WORSENING OF RASH BILATERAL, UPPER EXTREMITIES	2020-09-27 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152402; Age (years): 40; Sex: F; Race: MULTIPLE:				(b) (6)			
Cardiac disorders/ Atrial tachycardia/ ATRIAL TACHYCARDIA	2020-09-25 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Fall/ FALL	2020-10-03 (25)/ 2020-10-03 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Eye disorders/ Eyelid ptosis/ LEFT EYELID DROOP	2020-10-03 (25)/ 2020-10-25 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152402; Age (years): 40; Sex: F; Race: MULTIPLE:				(b) (6)			
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-10-03 (25)/ 2020-11-03 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Undifferentiated connective tissue disease/ UNDIFFERENTIATED CONNECTIVE TISSUE DISEASE	2020-11-05 (29)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Osteoporosis/ WORSENING OSTEOPOROSIS	2020-11-06 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152431; Age (years): 49; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-11-09 (8)/ 2020-11-12 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-09 (8)/ 2020-11-12 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152442; Age (years): 57; Sex: M; Race: MULTIPLE: (b) (6)							
Investigations/ Blood potassium decreased/ LOW POTASSIUM	2020-10-20 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3152465; Age (years): 33; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Herpes simplex/ HSV TYPE 1 OUTBREAK ON LIPS	2020-11-14 (3)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152468; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-22 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3152473; Age (years): 56; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Tooth infection/ INFECTION TOOTH #13	2020-11-02 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152494; Age (years): 32; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-15 10:37 (1)/ Ongoing	No/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152506; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-11-09 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152506; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Otitis media/ OTITIS MEDIA - R EAR	2020-11-16 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3162006; Age (years): 75; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-09 (78)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Fall/ FALL IN PARKING LOT	2020-11-10 (79)/ 2020-11-10 (79)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-11-10 (79)/ 2020-11-11 (80)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162006; Age (years): 75; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	2020-11-11 (80)/ 2020-11-12 (81)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Renal and urinary disorders/ Acute kidney injury/ ACUTE RENAL FAILURE	2020-11-11 (80)/ 2020-11-12 (81)	Yes/ Yes/ No	4	Yes/3 (2020-11-11/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-11-19 (88)/ 2020-11-19 (88)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162009; Age (years): 67; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-06 (10)/ 2020-08-10 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162009; Age (years): 67; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ ATYPICAL MIGRAINE	2020-08-06 (10)/ 2020-08-13 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Psychiatric disorders/ Anxiety/ WORSENED ANXIETY	2020-08-12 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162014; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-25 (47)/ 2020-10-28 (50)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162014; Age (years): 68; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ ANTERIOR CERVICAL LYMPHADENOPATHY, BILATERAL	2020-10-26 (48)/ 2020-10-27 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162015; Age (years): 77; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ ACUTE DIARRHEA	2020-08-08 (11)/ 2020-08-14 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Psoriasis/ PSORIASIS	2020-08-12 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162015; Age (years): 77; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ MUSCUOSKELETAL CHEST TIGHTNESS	2020-08-13 (16)/ 2020-08-13 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ INTERMITTENT DIARRHEA	2020-08-15 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Skin infection/ INFECTED ABRASIONS LEFT CALF	2020-10-20 (56)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162016; Age (years): 81; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS LEFT KNEE	/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA ANTERIOR UPPER CHEST	/ 2020-10-27 (91)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3162019; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL INFECTION UNSPECIFIED	2020-11-18 (85)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162019; Age (years): 52; Sex: M; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-11-20 (87)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162020; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL INFECTION, UNSPECIFIED	2020-11-18 (85)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162031; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-05 (40)/ 2020-10-12 (47)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162034; Age (years): 28; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-02 (67)/ 2020-11-11 (76)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162047; Age (years): 72; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	2020-08-10 (8)/ 2020-08-10 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ ACUTE BACK PAIN (DUE TO FALL)	2020-09-09 (10)/ 2020-10-10 (41)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162064; Age (years): 51; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-23 (53)/ 2020-10-27 (57)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIAS	2020-10-24 (54)/ 2020-10-27 (57)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Blood pressure systolic increased/ ELEVATION OF SYSTOLIC BLOOD PRESSURE	2020-10-26 (56)/ 2020-10-27 (57)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Blood pressure diastolic increased/ ELEVATION OF DIASTOLIC BLOOD PRESSURE	2020-10-26 (56)/ 2020-10-28 (58)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162064; Age (years): 51; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foreign body/ WOODEN FOREIGN BODY LEFT SOLE	2020-10-27 (57)/ 2020-11-04 (65)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural pain/ PAIN DUE TO REMOVAL OF WOODEN FOREIGN BODY LEFT SOLE	2020-11-04 (65)/ 2020-11-07 (68)	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162072; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ ACUTE VIRAL INFECTION, UNSPECIFIED	2020-11-08 (67)/ 2020-11-10 (69)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162073; Age (years): 67; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-17 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162087; Age (years): 22; Sex: F; Race: UNKNOWN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-30 (53)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162089; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL INFECTION UNSPECIFIED	2020-11-01 (55)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ BILATERAL CERVICAL ANTERIOR LYMPHADENOPATHY	2020-11-02 (56)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3162090; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ ACUTE VIRAL INFECTION, UNSPECIFIED	2020-11-09 (63)/ 2020-11-15 (69)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162095; Age (years): 46; Sex: M; Race: WHITE							
Infections and infestations/ Conjunctivitis/ RIGHT CONJUNCTIVITIS	2020-09-05 (27)/ 2020-09-16 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162101; Age (years): 26; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-13 (36)/ 2020-11-14 (68)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Viral infection/ VIRAL INFECTION, UNSPECIFIED	2020-10-22 (45)/ 2020-11-14 (68)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3162101; Age (years): 26; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-26 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162128; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-26 (13)/ 2020-10-03 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162130; Age (years): 56; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ DEPRESSION (ACUTE)	2020-09-12 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Haematuria/ ACUTE HEMATURIA	2020-09-18 (4)/ 2020-09-19 (5)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3162130; Age (years): 56; Sex: F; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ RENAL CALCULI	2020-09-28 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162139; Age (years): 69; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-23 (6)/ 2020-08-29 (12)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Vaccination complication/ FEBRILE REACTION TO SHINGRIX VACCINE	2020-10-17 (33)/ 2020-10-22 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162158; Age (years): 57; Sex: M; Race: ASIAN							
Metabolism and nutrition disorders/ Gout/ WORSENING OF GOUT (GOUT ATTACK) RIGHT ANKLE	2020-08-24 (5)/ 2020-09-29 (41)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162159; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-20 19:00 (1)/ 2020-09-03 06:30 (14)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162173; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-23 (3)/ 2020-08-30 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis/ BILATERAL FRONTAL SINUSITIS	2020-11-19 (63)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162176; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ Otitis externa/ LEFT OTITIS EXTERNA	2020-09-30 (14)/ 2020-10-28 (42)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162185; Age (years): 45; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ ACUTE VIRAL INFECTION, UNSPECIFIED	2020-11-16 (56)/ 2020-11-20 (60)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162219; Age (years): 53; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ RIGHT HAND TENDINITIS	2020-10-19 (19)/ 2020-11-23 (54)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162231; Age (years): 51; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Renal and urinary disorders/ Nephrolithiasis/ LEFT KIDNEY STONE	2020-09-14 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162254; Age (years): 35; Sex: M; Race: WHITE							
Nervous system disorders/ Presyncope/ VASOVAGAL EPISODE D/T BLOOD DRAW	2020-10-21 13:02 (28)/ 2020-10-21 13:09 (28)	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162263; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ ACUTE VIRAL INFECTION, UNSPECIFIED	2020-10-16 (12)/ 2020-10-23 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162273; Age (years): 38; Sex: F; Race: WHITE							
Psychiatric disorders/ Bipolar disorder/ WORSENING OF BIPOLAR DEPRESSION	2020-10-30 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Viral infection/ VIRAL INFECTION, UNSPECIFIED	2020-11-13 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162291; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ Otitis externa/ BILATERAL OTITIS EXTERNA	2020-10-19 17:00 (1)/ 2020-11-23 (36)	No/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162304; Age (years): 34; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEFT LOWER LEG INTERMITTENT CRAMPS	2020-11-03 (12)/ 2020-11-07 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172010; Age (years): 52; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-05 (57)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172038; Age (years): 34; Sex: F; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ RIGHT KIDNEY ACUTE NEPHROLITHIASIS	2020-08-29 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172038; Age (years): 34; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Metabolic acidosis/ PROFOUND METABOLIC ACIDOSIS	2020-09-01 (22)/ 2020-09-03 (24)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-01/ 2020-09-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE HYPOXEMIC RESPIRATOY FAILURE	2020-09-01 (22)/ 2020-09-03 (24)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-01/ 2020-09-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3172063; Age (years): 63; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Fibula fracture/ RIGHT ANKLE FIBULA FRACTURE	2020-08-20 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172069; Age (years): 68; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-09-04 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172071; Age (years): 65; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING INCREASED BLOOD PRESSURE	2020-10-06 (28)/ 2020-10-07 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172075; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ INTERMITTENT CHILLS	2020-08-16 (5)/ 2020-08-21 (10)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-08-17 (6)/ 2020-08-25 (14)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172088; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ ACUTE BRONCHITIS	2020-09-30 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3172102; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-20 (40)/ 2020-11-17 (68)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172105; Age (years): 75; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-18 (38)/ 2020-11-16 (67)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172144; Age (years): 44; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-25 (12)/ 2020-09-29 (16)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172180; Age (years): 61; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Joint injury/ LEFT KNEE TRAUMA DUE TO FALL ON 8-16-2020	2020-10-05 (49)/ 2020-10-07 (51)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172185; Age (years): 61; Sex: M; Race: WHITE							
Investigations/ International normalised ratio increased/ SUPRATHERAPEUTIC INTERNATIONAL NORMALIZED RATIO (INCREASED)	2020-09-07 (21)/ 2020-09-11 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Acute left ventricular failure/ ACUTE EXACERBATION OF SYSTOLIC HEART FAILURE	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172185; Age (years): 61; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILATION WITH RAPID VENTRICULAR RATE	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	2020-09-07 (21)/ 2020-09-15 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-15)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172211; Age (years): 53; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIB CAGE ARTHRALGIA (LEFT SIDED)	2020-09-25 (10)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172250; Age (years): 59; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ ACUTE EXACERBATION OF CONGESTION HEART FAILURE	2020-09-12 (24)/ 2020-09-16 (28)	Yes/ Yes/ No	3	Yes/3 (2020-09-12/ 2020-09-16)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172256; Age (years): 45; Sex: F; Race: WHITE							
Infections and infestations/ Folliculitis/ UNDERNEATH RIGHT BREAST FOLLICULITIS	2020-09-26 (10)/ 2020-10-13 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ UPPER RIGHT LEG PAIN	2020-09-28 (12)/ 2020-10-10 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172293; Age (years): 69; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEFT THIGH MUSCLE SPASM	2020-09-20 (28)/ 2020-09-22 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dyslipidaemia/ DYSLIPIDEMIA	2020-09-21 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEGS EDEMA	2020-09-21 (29)/ 2020-09-25 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172305; Age (years): 66; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ WORSENING OF DIZZINESS	2020-09-29 (9)/ 2020-09-29 (9)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172311; Age (years): 42; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ INTERMITTENT NAUSEA	2020-09-01 (8)/ 2020-09-04 (11)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ LEFT DELTOID IMJECTION SITE PAIN	2020-09-01 (8)/ 2020-09-06 (13)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ LEFT DELTOID INJECTION SITE TENDERNESS	2020-09-01 (8)/ 2020-09-06 (13)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172320; Age (years): 49; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-03 (40)/ 2020-10-12 (49)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ WORSENING OF BASELINE HYPERTENSION	2020-11-08 (76)/ 2020-11-08 (76)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172322; Age (years): 51; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ CHRONIC OBSTRUCTIVE PULMONARY DISEASE ACUTE EXACERBATION	2020-10-07 (14)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172322; Age (years): 51; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ WORSENING OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE	2020-10-10 (17)/ 2020-11-12 (50)	Yes/ Yes/ No	3	Yes/3 (2020-10-10/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3172325; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ ACUTE FLARE OF CHRONIC BACK PAIN	2020-10-11 (21)/ 2020-10-18 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172349; Age (years): 35; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Pregnancy, puerperium and perinatal conditions/ Abortion spontaneous/ MISCARRIAGE	2020-10-06 (42)/ 2020-10-13 (49)	Yes/ Yes/ No	2	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172352; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-09-21 (27)/ 2020-09-24 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-14 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172376; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-19 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172381; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	2020-10-23 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3172413; Age (years): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ ACUTE EXACERBATION OF BASELINE COPD	2020-11-17 07:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ACUTE EXACERBATION OF LEFT KNEE CHRONIC PAIN	2020-11-17 08:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172425; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ UNCONTROLLED HYPERTENSION	2020-11-16 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172435; Age (years): 58; Sex: F; Race: WHITE							
Vascular disorders/ Blood pressure inadequately controlled/ UNCONTROLLED BLOOD PRESSURE	2020-11-16 11:23 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172462; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION - (URI)	2020-11-09 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172467; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 SYMPTOMATIC	2020-10-29 (9)/ 2020-11-07 (18)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3182006; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Cystitis/ BLADDER INFECTION	2020-07-29 (3)/ 2020-08-05 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3182021; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-09 (43)/ 2020-10-29 (63)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3182040; Age (years): 52; Sex: M; Race: WHITE							
Nervous system disorders/ Facial paralysis/ BELL'S PALSY	2020-08-13 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3182047; Age (years): 67; Sex: F; Race: WHITE							
Eye disorders/ Eye pain/ LEFT EYE PAIN	2020-08-23 (26)/ 2020-08-24 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3182081; Age (years): 70; Sex: F; Race: WHITE							
Investigations/ Blood iron decreased/ LOW IRON	2020-09-16 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3182109; Age (years): 62; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-08-21 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3182110; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES RIGHT TRUNK	2020-09-18 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3182219; Age (years): 23; Sex: M; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ WORSENING OF ADHD	2020-08-28 (22)/ Ongoing	Yes/ Yes/ No	1	No	NA/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3182225; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS LEFT HAND	2020-08-15 (9)/ 2020-08-24 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3182227; Age (years): 69; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ LEFT ROTATOR CUFF TEAR	2020-09-25 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-10-06 (29)/ 2020-10-09 (32)	Yes/ Yes/ No	4	Yes/3 (2020-10-06/ 2020-10-09)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Syncope/ SYNCOPE	2020-10-24 (47)/ 2020-10-26 (49)	Yes/ Yes/ No	4	Yes/3 (2020-10-24/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3182230; Age (years): 64; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ CAT BITE RIGHT WRIST	2020-08-14 (8)/ 2020-08-23 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3182274; Age (years): 50; Sex: M; Race: WHITE							
Infections and infestations/ Gastroenteritis viral/ VIRAL GASTROENTERITIS	2020-08-12 02:30 (1)/ 2020-08-13 (3)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3182286; Age (years): 36; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ FACIAL RASH	2020-11-02 (54)/ 2020-11-16 (68)	Yes/ Yes/ No	1	No	NA/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3182292; Age (years): 19; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-08-23 (13)/ 2020-08-28 (18)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3182318; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-08 (27)/ 2020-09-16 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3182362; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-09-29 (9)/ 2020-10-08 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192031; Age (years): 73; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Intestinal obstruction/ BOWEL OBSTRUCTION	2020-09-19 (20)/ 2020-09-20 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3192229; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-20 (11)/ 2020-09-27 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192276; Age (years): 60; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Peptic ulcer/ PEPTIC ULCER	2020-10-13 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3192291; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Clostridium difficile colitis/ C-DIFF - COLITIIS	2020-11-02 (52)/ 2020-11-10 (60)	Yes/ Yes/ No	4	Yes/3 (2020-11-02/ 2020-11-10)	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192294; Age (years): 25; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY (LEFT SIDE NECK/PREAURICULAR)	2020-09-05 (21)/ 2020-09-08 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192464; Age (years): 64; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Proctalgia/ ANORECTAL PAIN	2020-10-26 (35)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192464; Age (years): 64; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrointestinal pain/ COLON SPASM	2020-11-03 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	UNKNOWN
Investigations/ Colonoscopy/ COLONOSCOPY	2020-11-03 (43)/ 2020-11-03 (43)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3192503; Age (years): 25; Sex: M; Race: WHITE							
Congenital, familial and genetic disorders/ Hydrocele/ RIGHT TESTICULAR HYDROCELE	2020-09-08 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192522; Age (years): 48; Sex: F; Race: WHITE							
Surgical and medical procedures/ Fracture treatment/ 5TH PHALANX FRACTURE LEFT HAND SURGICALLY REPAIRED	2020-09-11 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SURGERY PERFORMED 19 SEP 2020 DUE TO FRACTURE
Subject ID: US3192614; Age (years): 60; Sex: M; Race: WHITE							
Cardiac disorders/ Pericarditis/ PERICARDITIS	2020-09-11 (12)/ 2020-09-15 (16)	Yes/ Yes/ No	2	Yes/3 (2020-09-14/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3192643; Age (years): 41; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION	2020-10-16 (17)/ 2020-10-28 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Road traffic accident/ BICYCLE ACCIDENT	2020-10-16 (17)/ 2020-10-28 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192643; Age (years): 41; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin abrasion/ ABRASIONS ON ARMS AND KNEES	2020-10-16 (17)/ 2020-10-28 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Haematoma/ L HIP HEMATOMA	2020-10-16 (17)/ 2020-10-28 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3192704; Age (years): 64; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-11-04 (33)/ 2020-11-20 (49)	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192791; Age (years): 29; Sex: F; Race: ASIAN							
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-10-17 (6)/ 2020-10-23 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192855; Age (years): 51; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ CHEST CONTUSSION	2020-10-22 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202006; Age (years): 71; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-23 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202010; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-09-03 (30)/ 2020-09-05 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202030; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-08-11 (6)/ 2020-08-22 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-08-13 (8)/ 2020-08-18 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202038; Age (years): 26; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-02 (23)/ 2020-10-13 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202039; Age (years): 45; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS	2020-08-31 (26)/ 2020-09-10 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3202047; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-08-25 (19)/ 2020-09-03 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID - 19	2020-11-05 (56)/ 2020-11-21 (72)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202060; Age (years): 20; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ URI- PATHOGEN RHINOVIRUS	2020-11-14 (66)/ 2020-11-20 (72)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202066; Age (years): 24; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-16 (9)/ 2020-08-21 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-16 (9)/ 2020-08-21 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3202097; Age (years): 41; Sex: F; Race: WHITE							
Nervous system disorders/ Neuralgia/ NERVE PAIN IN NECK	2020-09-29 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3202116; Age (years): 41; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Amenorrhoea/ AMENORRHEA	2020-09-26 (5)/ 2020-10-22 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202151; Age (years): 31; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Plantar fasciitis/ BILATERAL PLANTAR FASCIITIS	2020-09-08 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3202152; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-11 (3)/ 2020-10-01 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202171; Age (years): 52; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-22 (13)/ 2020-09-24 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 (13)/ 2020-09-25 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202171; Age (years): 52; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-22 (13)/ 2020-09-27 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-22 (13)/ 2020-09-27 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION OF UNKNOWN ETIOLOGY	2020-09-22 (13)/ 2020-09-27 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202172; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Tooth infection/ DENTAL INFECTION	2020-09-07 (26)/ 2020-09-21 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3202188; Age (years): 54; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ SPRAINED RIGHT KNEE	2020-09-18 (8)/ 2020-10-01 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202190; Age (years): 25; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION TO LEFT SHIN	2020-09-16 (34)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3202210; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID - 19	2020-11-12 (57)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202225; Age (years): 67; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH	2020-11-15 (60)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202234; Age (years): 34; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION LEFT 4TH DIGIT	2020-10-15 (29)/ 2020-10-22 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3202250; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION UNKNOWN CAUSE	2020-10-13 (21)/ 2020-10-16 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ WORSENING DIARRHEA	2020-10-13 (21)/ 2020-10-17 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202255; Age (years): 55; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION TO LEFT HAND INDEX FINGER	2020-10-08 (21)/ 2020-10-18 (31)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3202278; Age (years): 34; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Hiatus hernia/ HIATAL HERNIA	2020-09-12 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3202303; Age (years): 30; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-31 (41)/ 2020-11-04 (45)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202303; Age (years): 30; Sex: F; Race: MULTIPLE: (b) (6)							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-11-08 (49)/ 2020-11-13 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202311; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-21 (28)/ 2020-10-27 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Tooth infection/ INFECTED TOOTH	2020-10-27 (34)/ 2020-11-02 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202319; Age (years): 34; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-18 (25)/ 2020-09-18 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202319; Age (years): 34; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-18 (25)/ 2020-09-22 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-22 (29)/ 2020-09-22 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ ACID REFLUX	2020-11-17 (47)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202332; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER UNKNOWN CAUSE	2020-09-19 (25)/ 2020-09-24 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202337; Age (years): 66; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-11 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202346; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID - 19	2020-10-09 (16)/ 2020-10-22 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202369; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ Viral upper respiratory tract infection/ URI- PROBABLY VIRAL	2020-10-17 (19)/ 2020-10-23 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202371; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-10-05 (7)/ 2020-10-06 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202405; Age (years): 30; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ DEPRESSION	2020-10-13 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212011; Age (years): 36; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Arthropod sting/ BEE STING OF RIGHT MIDDLE FINGER	2020-11-06 (68)/ 2020-11-11 (73)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212019; Age (years): 45; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Iron deficiency anaemia/ IRON DEFICIENCY ANEMIA	2020-09-09 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212019; Age (years): 45; Sex: F; Race: WHITE							
Vascular disorders/ Lymphoedema/ WORSENING LYMPHEDEMA, LEFT LOWER LEG	2020-09-11 (29)/ 2020-09-15 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Asthma/ ACUTE ASTHMA EXACERBATION	2020-10-19 (32)/ 2020-10-23 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-11 (55)/ 2020-11-14 (58)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-11 (55)/ 2020-11-20 (64)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212019; Age (years): 45; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-11-11 (55)/ 2020-11-20 (64)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212044; Age (years): 31; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	2020-08-16 (12)/ 2020-08-23 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-09-29 (28)/ 2020-10-21 (50)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212048; Age (years): 31; Sex: M; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-22 (51)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212052; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ POST OPERATIVE PAIN	2020-09-30 (29)/ 2020-10-03 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212056; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Conjunctivitis bacterial/ BACTERIAL CONJUNCTIVITIS, RIGHT EYE	2020-09-15 (14)/ 2020-09-22 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212094; Age (years): 61; Sex: M; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	2020-10-21 (50)/ 2020-10-22 (51)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212094; Age (years): 61; Sex: M; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-26 (55)/ 2020-10-27 (56)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212096; Age (years): 67; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bursitis/ WORSENING BURSITIS OF RIGHT HIP	2020-10-09 (32)/ 2020-10-10 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF LEFT KNEE DEGENERATIVE JOINT DISEASE	2020-10-09 (32)/ 2020-10-10 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3212096; Age (years): 67; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION OF LEFT INDEX FINGER	2020-10-29 (52)/ 2020-10-29 (52)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212104; Age (years): 45; Sex: M; Race: WHITE							
Infections and infestations/ Otitis externa/ OTITIS EXTERNA	2020-10-05 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3212112; Age (years): 28; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19 POSITIVE	2020-10-14 (66)/ 2020-10-26 (78)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212129; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tendon rupture/ RIGHT 5TH DIGIT TENDON RUPTURE	2020-09-17 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Subject ID: US3212129; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Post-traumatic pain/ BACK PAIN DUE TO MOTOR VEHICLE ACCIDENT	2020-10-23 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Post-traumatic pain/ CERVICAL PAIN DUE TO MOTOR VEHICLE ACCIDENT	2020-10-23 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT	2020-10-23 (46)/ 2020-10-23 (46)	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3212129; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ FRACTURED LEFT FOOT	2020-11-05 (59)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3212133; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-11-10 (61)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212143; Age (years): 48; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	2020-08-12 12:38 (1)/ 2020-08-12 12:39 (1)	No/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212149; Age (years): 62; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF RIGHT KNEE OSTEOARTHRITIS PAIN	2020-08-20 (9)/ 2020-08-27 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212150; Age (years): 53; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Joint injury/ RIGHT WRIST INJURY	2020-09-03 (23)/ 2020-09-03 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Limb injury/ RIGHT 4TH DIGIT INURY	2020-09-03 (23)/ 2020-09-03 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Limb injury/ RIGHT THIGH INJURY	2020-09-03 (23)/ 2020-09-03 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED WITH SEQUELAE: RIGHT THIGH BRUISE

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212150; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-24 (40)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212151; Age (years): 64; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ 5TH METATARSAL FX, LEFT LOWER EXTREMITY	2020-09-25 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Infections and infestations/ COVID-19/ COVID-19	2020-11-05 (58)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212152; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	2020-08-12 17:50 (1)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212163; Age (years): 18; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	2020-08-13 11:58 (1)/ 2020-08-13 11:59 (1)	No/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212166; Age (years): 68; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ WORSENING OF OSTEOARTHRITIS OF LUMBAR SPINE	2020-09-14 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Acute sinusitis/ ACUTE SINUSITIS	2020-11-12 (65)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212169; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-09-29 (14)/ 2020-10-09 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212171; Age (years): 21; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Post-traumatic pain/ POST-TRAUMATIC RIGHT HIP PAIN	2020-10-01 (21)/ 2020-10-14 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212175; Age (years): 51; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF LOWER BACK PAIN	2020-09-14 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3212180; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-16 (67)/ 2020-11-19 (70)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Vulvovaginal candidiasis/ VAGINAL CANDIDIASIS	2020-11-19 (70)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212187; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP PHARYNGITIS	2020-09-25 (9)/ 2020-10-07 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212188; Age (years): 20; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH	2020-10-09 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3212192; Age (years): 45; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-08 (18)/ 2020-10-10 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-09 (19)/ 2020-10-10 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212192; Age (years): 45; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-09 (19)/ 2020-10-10 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-09 (19)/ 2020-10-10 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-09 (19)/ 2020-10-10 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212210; Age (years): 40; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS - RIGHT JAWLINE	2020-08-31 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212219; Age (years): 54; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-08-21 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212233; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-18 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3212263; Age (years): 53; Sex: F; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ NEPHROLITHIASIS	2020-10-08 (22)/ 2020-10-15 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT CERVICAL LYMPHADENOPATHY-ACUTE IPSILATERAL TO INJECTION SITE	2020-11-06 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212272; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-06 (20)/ 2020-10-15 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212276; Age (years): 81; Sex: F; Race: WHITE							
Eye disorders/ Conjunctivitis allergic/ ACUTE CONJUNCTIVITIS - ALLERGIC	2020-09-11 (23)/ 2020-09-14 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212290; Age (years): 50; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Ecchymosis/ ECCHYMOSIS BILATERAL ARMS/ANTECUBITAL FOSSA	2020-08-25 12:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-09 (49)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212304; Age (years): 50; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-13 (53)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212315; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-17 (55)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212329; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ ACUTE EXACERBATION OF CHRONIC LOWER BACK PAIN	2020-09-06 (7)/ 2020-09-14 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212337; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-15 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212376; Age (years): 36; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Ovarian cyst/ CYST OF LEFT OVARY	2020-09-22 (13)/ 2020-09-23 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Enteritis/ ENTERITIS	2020-09-22 (13)/ 2020-09-29 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212381; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-12 (18)/ 2020-11-19 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-13 (19)/ 2020-11-19 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212396; Age (years): 55; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-10-16 13:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT FOREARM PAIN	2020-10-16 13:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Hypoaesthesia/ RIGHT HAND NUMBNESS	2020-10-16 13:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212396; Age (years): 55; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT	2020-10-16 13:00 (1)/ 2020-10-16 13:15 (1)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: MOTOR VEHICLE ACCIDENT TOOK PLACE ON 16OCT2020. SUBJECT WAS LEFT WITH: RIGHT FOREARM PAIN, RIGHT HAND NUMBNESS, NECK PAIN.
Subject ID: US3212400; Age (years): 32; Sex: M; Race: ASIAN							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-11-02 (25)/ 2020-11-06 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3212404; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ Enterovirus infection/ UPPER RESPIRATORY INFECTION DUE TO ENTEROVIRUS/RHINOVIRUS	2020-11-08 (24)/ 2020-11-14 (30)	Yes/ Yes/ No	1	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222015; Age (years): 85; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-06 15:33 (1)/ 2020-08-07 16:03 (2)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222031; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION - EXACERBATION	2020-08-07 12:51 (1)/ Ongoing	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3222048; Age (years): 59; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ FINGER LACERATION LEFT HAND	2020-09-02 (26)/ 2020-09-02 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3222048; Age (years): 59; Sex: F; Race: WHITE							
Surgical and medical procedures/ Dental operation/ DENTAL SURGERY	2020-11-18 (40)/ 2020-11-18 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222059; Age (years): 84; Sex: F; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ NEW ONSET-ATRIAL FIBRILLATION	2020-09-03 (27)/ 2020-09-05 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-05)/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Essential hypertension/ ESSENTIAL HYPERTENSION	2020-09-05 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3222068; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-24 (16)/ 2020-10-05 (27)	Yes/ Yes/ No	4	Yes/3 (2020-09-24/ 2020-10-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3222078; Age (years): 38; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-24 (14)/ 2020-08-24 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222089; Age (years): 72; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-31 (50)/ 2020-11-04 (54)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222101; Age (years): 71; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA	2020-09-03 (23)/ 2020-09-03 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222111; Age (years): 60; Sex: M; Race: OTHER: (b) (6)							
Psychiatric disorders/ Depression/ DEPRESSION	2020-10-27 (47)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3222114; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTION, LEFT GREAT TOE	2020-08-31 (20)/ 2020-09-15 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222142; Age (years): 82; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Constipation/ CONSTIPATION	2020-10-26 (43)/ 2020-10-29 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-10-26 (43)/ 2020-10-29 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222147; Age (years): 76; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2020-08-17 (4)/ 2020-08-17 (4)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222189; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Precancerous condition/ PRE-CANCEROUS ULCER OF STOMACH AND ESOPHAGUS	2020-09-21 (4)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-21/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Psychiatric disorders/ Alcohol abuse/ ALCOHOL ABUSE	2020-10-10 (23)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-10/)/6	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3222197; Age (years): 27; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN LYMPH NODES	2020-11-09 (55)/ Ongoing	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Throat tightness/ THROAT TIGHTNESS	2020-11-11 (57)/ Ongoing	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222216; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-13 (35)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222242; Age (years): 57; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Thyroid cancer/ THYROID CANCER	2020-10-01 (16)/ 2020-10-20 (35)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3222260; Age (years): 68; Sex: M; Race: WHITE							
Surgical and medical procedures/ Tooth extraction/ MULTIPLE DENTAL EXTRACTIONS	2020-11-14 (55)/ 2020-11-14 (55)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222279; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-09 (52)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222279; Age (years): 54; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE PAIN	2020-11-09 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3222284; Age (years): 62; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3222285; Age (years): 50; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Meniscus injury/ MINISCUS TEAR - RIGHT	2020-09-10 (20)/ 2020-10-15 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3222304; Age (years): 64; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-01 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222305; Age (years): 52; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Glucose tolerance impaired/ PRE DIABETES MELLITUS	2020-10-12 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-10-12 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222311; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-28 (6)/ 2020-09-30 (8)	Yes/ Yes/ No	4	Yes/3 (2020-09-28/ 2020-09-30)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222315; Age (years): 72; Sex: F; Race: WHITE							
Surgical and medical procedures/ Hip arthroplasty/ ARTHROPLASTY - RIGHT HIP	2020-09-09 (17)/ 2020-11-09 (78)	Yes/ Yes/ No	4	Yes/3 (2020-09-09/ 2020-09-10)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222321; Age (years): 18; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ ACNE VULGARIS	2020-10-20 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222326; Age (years): 44; Sex: M; Race: WHITE							
Nervous system disorders/ Tarsal tunnel syndrome/ TWISTED TARSAL NERVE	2020-10-09 (18)/ 2020-10-09 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3222363; Age (years): 59; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-08 (15)/ 2020-10-19 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222367; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-11-23 (57)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-23/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222420; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	2020-10-14 (16)/ 2020-10-27 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222427; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Sialoadenitis/ INFECTED SALIVARY GLAND	2020-09-11 (11)/ 2020-09-18 (18)	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222430; Age (years): 60; Sex: M; Race: WHITE							
Surgical and medical procedures/ Jaw operation/ JAW SURGERY	2020-11-05 (36)/ 2020-11-06 (37)	Yes/ Yes/ No	3	Yes/3 (2020-11-05/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3222510; Age (years): 56; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS	2020-11-06 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222574; Age (years): 53; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-10 (2)/ 2020-10-20 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222577; Age (years): 63; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222590; Age (years): 52; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rosacea/ ROSACEA EXACERBATION	2020-10-14 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3222611; Age (years): 55; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Gait disturbance/ GAIT DYSFUNCTION AND ADL'S AND SELF-CARE DEFICITS	2020-10-29 (15)/ 2020-11-10 (27)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: NO BILATERAL FEET CONTROL, RIGHT SIDE OF BODY PARALYSIS.

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222611; Age (years): 55; Sex: M; Race: WHITE							
Nervous system disorders/ Aphasia/ MILD EXPRESSIVE AND RECEPTIVE AND RECEPTIVE APHASIA.	2020-10-29 (15)/ 2020-11-10 (27)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: RESIDUAL EFFECTS FROM CVA
Nervous system disorders/ Basal ganglia haemorrhage/ LEFT BASAL GANGLIA HEMORRHAGE	2020-10-29 (15)/ 2020-11-10 (27)	Yes/ Yes/ No	4	Yes/3 (2020-10-29/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-29 (15)/ 2020-11-10 (27)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: ALTHOUGH NOW TREATED WITH MEDICATION WILL CONTINUE WITH DIAGNOSIS

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222611; Age (years): 55; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Dyslipidaemia/ DYSLIPIDEMIA	2020-10-29 (15)/ 2020-11-15 (32)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: THIS HAS BEEN TREATED WITH MEDICATION HOWEVER WILL NEVER RESOLVE WITHOUT MEDICATION.
Subject ID: US3222613; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ FINGER LACERATION	2020-11-03 (16)/ 2020-11-13 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222636; Age (years): 61; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ CERVICAL MUSCLE STRAIN	2020-10-14 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222640; Age (years): 64; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-10-26 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ LEFT SIDE PAIN/MUSCLE ACHES	2020-10-26 (3)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ LEFT SIDE BACK PAIN	2020-11-16 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222653; Age (years): 45; Sex: F; Race: WHITE							
Investigations/ Oxygen saturation decreased/ DECREASED O2 AT PCP	2020-11-10 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3232054; Age (years): 38; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 (10)/ 2020-09-25 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Head discomfort/ HEAD CONGESTION	2020-09-23 (10)/ 2020-09-28 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3232056; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ PANSINUSITIS	2020-09-30 (17)/ 2020-10-03 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3232056; Age (years): 72; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-30 (17)/ 2020-10-03 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232093; Age (years): 68; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-09-07 (17)/ 2020-09-07 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232097; Age (years): 67; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-06 (6)/ 2020-10-09 (9)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232103; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-17 (26)/ 2020-10-24 (33)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232145; Age (years): 20; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-02 16:51 (2)/ 2020-10-08 09:00 (7)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242002; Age (years): 35; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-08-09 (4)/ 2020-09-02 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242022; Age (years): 80; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-09-22 (14)/ 2020-09-30 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-12 (34)/ 2020-10-18 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3242026; Age (years): 67; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-18 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242040; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-28 (21)/ 2020-10-17 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242051; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ Otitis media acute/ ACUTE OTITIS MEDIA, RIGHT	2020-09-19 (9)/ 2020-10-02 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Ankle fracture/ TRIMALLEOLAR ANKLE FRACTURE, RIGHT	2020-11-01 (52)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-02/ 2020-11-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Subject ID: US3242053; Age (years): 67; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ WORSENING HYPERCHOLESTEROLEMIA	2020-11-02 (55)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242065; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS, LOWER LEFT LEG	2020-09-19 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Peripheral vascular disorder/ WORSENING OF PERIPHERAL VASCULAR DISEASE	2020-09-19 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Vascular disorders/ Phlebitis/ PHIEBITIS	2020-09-19 (9)/ 2020-10-03 (23)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242067; Age (years): 73; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-06 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242087; Age (years): 63; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM PAIN	2020-10-31 (48)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242089; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-01 (52)/ 2020-11-09 (60)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242100; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ UNCONTROLLED HYPERTENSION	2020-09-09 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242112; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-22 (38)/ 2020-11-03 (50)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242116; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-09-17 (3)/ 2020-09-21 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242132; Age (years): 65; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL CARCINOMA, LOWER LEG, LEFT	2020-09-01 (15)/ 2020-10-12 (56)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242171; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-25 (6)/ 2020-08-29 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-18 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242186; Age (years): 23; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-08-29 (9)/ 2020-09-22 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242189; Age (years): 55; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE	2020-09-21 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242230; Age (years): 75; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-07 (44)/ 2020-11-17 (54)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242241; Age (years): 71; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ WORSENING COPD	2020-09-08 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-29 (5)/ 2020-10-06 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242246; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Kidney infection/ KIDNEY INFECTION	2020-09-04 (8)/ 2020-09-08 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-09-11 (15)/ 2020-10-02 (36)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Bullous impetigo/ BULLOUS IMPETIGO	2020-10-13 (9)/ 2020-11-10 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242254; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Sciatica/ SCIATICA	2020-09-23 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242254; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ BENIGN PROSTATIC HYPERPLASIA (BPH)	2020-09-23 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242258; Age (years): 76; Sex: F; Race: WHITE							
Infections and infestations/ Pneumonia/ COMMUNITY ACQUIRED PNEUMONIA	2020-09-15 (16)/ 2020-10-22 (53)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA, SEVERE PERSISTENT	2020-10-05 (36)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242264; Age (years): 49; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Facial bones fracture/ BROKEN NOSE	2020-11-20 (54)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Skin laceration/ HEAD LACERATION	2020-11-20 (54)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-20/ 2020-11-22)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3242271; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-28 (28)/ 2020-10-04 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242272; Age (years): 26; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Viral upper respiratory tract infection/ VIRAL UPPER RESPIRATORY INFECTION	2020-09-26 (26)/ 2020-10-02 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242278; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-16 (47)/ 2020-11-23 (54)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242279; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ DENTAL ABSCESS	2020-09-14 (13)/ 2020-09-20 (19)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242291; Age (years): 64; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma of skin/ SQUAMOUS CELL CARCINOMA (SCALP)	2020-10-15 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242304; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ DENTAL ABSCESS	2020-09-15 (8)/ 2020-09-24 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242308; Age (years): 58; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Chest discomfort/ CHEST PRESSURE	2020-11-23 (43)/ 2020-11-23 (43)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242348; Age (years): 48; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-11-06 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242352; Age (years): 38; Sex: F; Race: ASIAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-14 (27)/ 2020-11-20 (33)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242365; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Acute sinusitis/ ACUTE SINUSITIS	2020-10-28 (9)/ 2020-11-10 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242385; Age (years): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-01 (7)/ 2020-11-04 (10)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242389; Age (years): 56; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ WORSENING GERD	2020-10-29 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-03 (9)/ 2020-11-09 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242397; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-10-31 (5)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242407; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-11-04 15:34 (35)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252005; Age (years): 55; Sex: F; Race: NOT REPORTED							
Infections and infestations/ Oral candidiasis/ ORAL CANDIDIASIS	2020-09-24 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252020; Age (years): 24; Sex: M; Race: NOT REPORTED							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-08-13 (10)/ 2020-08-22 (19)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252021; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-27 (24)/ 2020-09-04 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252065; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-08-13 (7)/ 2020-08-14 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252083; Age (years): 33; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-10-20 (47)/ 2020-11-02 (60)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252089; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP PAIN	2020-09-01 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Sinusitis/ SINUSITIS	2020-11-13 (66)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252119; Age (years): 57; Sex: M; Race: WHITE							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-14 (37)/ 2020-10-20 (43)	Yes/ Yes/ No	4	Yes/2/3 (2020-10-14/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252130; Age (years): 79; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ UNSPECIFIED DENTAL FRACTURE	2020-08-28 (17)/ 2020-09-11 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3252211; Age (years): 34; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-02 (19)/ 2020-10-11 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252212; Age (years): 63; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-28 (13)/ 2020-10-12 (27)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252230; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-13 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252267; Age (years): 38; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastric ulcer/ GASTRIC ULCER	2020-10-13 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252276; Age (years): 54; Sex: M; Race: WHITE							
Endocrine disorders/ Hypogonadism/ HYPOGONADISM	2020-09-02 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3252287; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ WISDOM TEETH PAIN	2020-09-15 (26)/ 2020-09-15 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3252301; Age (years): 52; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA UNSPECIFIC	2020-09-17 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3252334; Age (years): 45; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Costochondritis/ COSTOCHONDRITIS OF THE RIGHT STERNUM	2020-10-03 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252347; Age (years): 60; Sex: M; Race: NOT REPORTED							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ BENIGN PROSTATIC HYPERPLASIA	2020-10-10 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3252374; Age (years): 66; Sex: F; Race: NOT REPORTED							
Injury, poisoning and procedural complications/ Tooth fracture/ DENTAL FRACTURE	2020-09-11 (15)/ 2020-09-11 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252381; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES (FACIAL)	2020-10-17 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3252408; Age (years): 47; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ DENTAL CARIES	2020-09-28 (28)/ 2020-09-28 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3252454; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Laryngitis/ LARYNGITIS	2020-10-02 (23)/ 2020-10-06 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252465; Age (years): 60; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS	2020-10-13 00:00 (32)/ 2020-10-13 16:00 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252495; Age (years): 25; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-10-10 (23)/ 2020-10-15 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252512; Age (years): 74; Sex: M; Race: ASIAN							
Metabolism and nutrition disorders/ Hyperlipidaemia/ NEW DIAGNOSIS OF HYPERLIPIDEMIA	2020-10-09 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3252542; Age (years): 32; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media acute/ LEFT ACUTE OTITIS MEDIA.	2020-10-01 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252553; Age (years): 74; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ankle fracture/ RIGHT ANKLE FRACTURE.	2020-10-13 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252553; Age (years): 74; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ankle fracture/ RIGHT ANKLE FRACTURE	2020-10-23 00:00 (29)/ Ongoing	Yes/ Yes/ No	2	Yes/3	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252602; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-11-06 (8)/ 2020-11-06 (8)	Yes/ Yes/ No	3	Yes/3 (2020-11-06/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3252627; Age (years): 44; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-28 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3252638; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-24 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252657; Age (years): 43; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Glucose tolerance impaired/ PRE-DIABETES	2020-11-13 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-11-13 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFICIENT	2020-11-13 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3262099; Age (years): 61; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC CONFIRMED COVID POSITIVE INFECTION	2020-10-12 (40)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272005; Age (years): 45; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-07-30 00:00 (1)/ 2020-07-31 (3)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-07-30 00:00 (1)/ 2020-08-01 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-07-30 00:00 (1)/ 2020-08-02 00:00 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272005; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-08 (103)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-08 (103)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-11-08 (103)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-11-08 (103)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272005; Age (years): 45; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-08 (103)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-08 (103)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-09 (104)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-09 (104)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272005; Age (years): 45; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-11-09 (104)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	2020-11-09 (104)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHES	2020-11-10 (105)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-12 (107)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272005; Age (years): 45; Sex: F; Race: WHITE							
Infections and infestations/ Oral candidiasis/ ORAL CANDIDIASIS	2020-11-15 (110)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272010; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-10 (75)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272015; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Carpal tunnel syndrome/ WORSENING CARPAL TUNNEL (LEFT WRIST)	2020-08-26 (28)/ 2020-08-26 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272026; Age (years): 46; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID19	2020-11-08 (62)/ Ongoing	Yes/ Yes/ No	4	Yes/2/3 (2020-11-16/)/4	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3272031; Age (years): 67; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Breast cancer stage I/ STAGE 1 LEFT BREAST CANCER	2020-08-17 (17)/ 2020-08-27 (27)	Yes/ Yes/ No	2	Yes/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3272035; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING RIGHT KNEE PAIN	2020-02-03 (-182)/ 2020-09-22 (51)	No/ Yes/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272055; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-05 (33)/ 2020-10-27 (55)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272064; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-25 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272070; Age (years): 74; Sex: M; Race: WHITE							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-01 (29)/ 2020-10-01 (29)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ NONE	FATAL

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272085; Age (years): 58; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ WORSENING INTERMITTENT CHEST WALL PAIN NON CARDIAC	2020-10-07 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-09/ 2020-10-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-05 (63)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272097; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ POSITIVE COVID 19	2020-11-15 (68)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272101; Age (years): 42; Sex: M; Race: WHITE							
Cardiac disorders/ Tachycardia/ TRACHYCARDIA	2020-08-16 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF BILATERAL KNEE PAIN	2020-10-19 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272104; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-20 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272104; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ ALL OVER BODY ACHES	2020-10-20 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-20 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Myalgia/ ALL OVER MUSCLE ACHES	2020-10-20 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Subject ID: US3272104; Age (years): 68; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-20 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-20 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272107; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-09-09 (30)/ 2020-09-12 (33)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272125; Age (years): 31; Sex: M; Race: WHITE							
Infections and infestations/ Campylobacter infection/ CAMPYLOBACTER	2020-08-15 (3)/ 2020-08-19 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3272125; Age (years): 31; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-05 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-05 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-05 (26)/ 2020-10-07 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272125; Age (years): 31; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (GENERALIZED)	2020-10-05 (26)/ 2020-10-07 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-05 (26)/ 2020-10-07 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272135; Age (years): 54; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-07 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272135; Age (years): 54; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-07 (24)/ 2020-10-12 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-10 (27)/ 2020-10-12 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-11 (28)/ 2020-10-11 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-12 (29)/ 2020-11-19 (67)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272142; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-10-27 (43)/ 2020-11-06 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272143; Age (years): 40; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-29 (16)/ 2020-09-03 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-08-30 (17)/ 2020-09-02 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-31 (18)/ 2020-09-01 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272144; Age (years): 29; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 ILLNESS	2020-11-02 (53)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-12/ 2020-11-19)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272154; Age (years): 30; Sex: M; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT HYPERACTIVITY DISORDER	2020-09-11 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Nervous system disorders/ Shift work disorder/ SHIFT WORK SLEEP DISORDER	2020-10-30 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272174; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-05 (53)/ 2020-11-16 (64)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272184; Age (years): 41; Sex: F; Race: WHITE							
Eye disorders/ Lacrimation increased/ EPIPHORA	2020-10-05 (20)/ 2020-10-06 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-05 (20)/ 2020-10-06 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEBRILE (100.5 F)	2020-10-05 (20)/ 2020-10-06 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-10-05 (20)/ 2020-10-06 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272184; Age (years): 41; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 (20)/ 2020-10-06 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS (NASAL)	2020-10-05 (20)/ 2020-10-06 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID 19	2020-10-29 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Conjunctivitis/ CONJUNCTIVITIS OD	2020-11-11 (57)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272186; Age (years): 24; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-10-30 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272191; Age (years): 36; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ DENTAL IMPLANT UPPER RIGHT LATERAL TOOTH - CARIES	2020-10-01 (16)/ 2020-10-29 (44)	Yes/ Yes/ No				DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3272195; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-30 (44)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-07/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272195; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19 pneumonia/ PNEUMONIA SECONDARY TO COVID 19 POSITIVE INFECTION	2020-11-07 (52)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-07/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Hypoxia/ HYPOXIA	2020-11-07 (52)/ 2020-11-12 (57)	Yes/ Yes/ No	3	Yes/3 (2020-11-07/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Vulvovaginal candidiasis/ VAGINAL CANDIDIASIS	2020-11-15 (60)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272196; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-05 (51)/ 2020-11-19 (65)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272206; Age (years): 65; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-30 (14)/ 2020-10-07 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-30 (14)/ 2020-10-07 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-30 (14)/ 2020-10-07 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-30 (14)/ 2020-10-07 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272206; Age (years): 65; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-30 (14)/ 2020-10-07 (21)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-30 (14)/ 2020-10-07 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272210; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-28 (8)/ 2020-10-08 (18)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272219; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-18 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272251; Age (years): 37; Sex: F; Race: WHITE							
Infections and infestations/ Vulvovaginal candidiasis/ VAGINAL CANDIDIASIS	2020-10-01 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-02 (40)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-11-02 (40)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-02 (40)/ 2020-11-18 (56)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272271; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-23 (32)/ 2020-11-17 (57)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272274; Age (years): 62; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS IN LEFT THUMB	2020-10-15 (20)/ 2020-11-09 (45)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272277; Age (years): 45; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-09 (19)/ 2020-09-19 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272287; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Tonsillitis/ TONSILLITIS	2020-10-13 (20)/ 2020-10-21 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272302; Age (years): 31; Sex: F; Race: WHITE							
Endocrine disorders/ Hypothyroidism/ WORSENING OF HYPOTHYROIDISM	2020-09-04 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272305; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-20 (29)/ 2020-11-01 (41)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Cerumen impaction/ CERUMEN IMPACTION L EAR	2020-10-21 (30)/ 2020-11-17 (57)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Cerumen impaction/ RIGHT EAR IMPACTION	2020-11-17 (57)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272306; Age (years): 79; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-16 (25)/ 2020-09-25 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272317; Age (years): 81; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-06 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272329; Age (years): 33; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-10-22 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ COVID-19/ COVID 19	2020-10-28 (34)/ 2020-11-09 (46)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272342; Age (years): 57; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-01 (8)/ 2020-10-06 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-01 (8)/ 2020-10-08 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Ageusia/ NEW LOSS OF TASTE	2020-10-01 (8)/ 2020-10-08 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Anosmia/ NEW LOSS OF SMELL	2020-10-01 (8)/ 2020-10-08 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272342; Age (years): 57; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHES	2020-10-01 (8)/ 2020-10-08 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-10-01 (8)/ 2020-10-08 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-01 (8)/ 2020-10-10 (17)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-01 (8)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272342; Age (years): 57; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-01 (8)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-01 (8)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272347; Age (years): 65; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-11-02 (43)/ 2020-11-07 (48)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-02 (43)/ 2020-11-08 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272347; Age (years): 65; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-06 (47)/ 2020-11-07 (48)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272351; Age (years): 46; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-10-05 (12)/ 2020-10-06 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272357; Age (years): 41; Sex: F; Race: NOT REPORTED							
Infections and infestations/ COVID-19/ COVID 19	2020-11-09 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272361; Age (years): 24; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ COVID-19/ COVID-19	2020-09-29 (7)/ 2020-10-23 (31)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272362; Age (years): 40; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-10-07 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-07 (14)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-07 (14)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-07 (14)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272362; Age (years): 40; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 (14)/ 2020-10-16 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-07 (14)/ 2020-10-18 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272381; Age (years): 46; Sex: M; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-12 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272381; Age (years): 46; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-12 (22)/ 2020-11-12 (22)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-12 (22)/ 2020-11-18 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-16 (26)/ 2020-11-16 (26)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-11-16 (26)/ 2020-11-17 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272381; Age (years): 46; Sex: M; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-17 (27)/ 2020-11-18 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-11-17 (27)/ 2020-11-18 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282003; Age (years): 69; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ BICEP TENDONITIS OF RIGHT SHOULDER	2020-09-01 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282007; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Conjunctivitis bacterial/ ACUTE BACTERIAL CONJUNCTIVITIS OF RIGHT EYE	2020-11-18 (72)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3282015; Age (years): 73; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-20 (15)/ 2020-08-30 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3282037; Age (years): 76; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-26 (15)/ 2020-08-29 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282037; Age (years): 76; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-08-28 (17)/ 2020-08-29 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282053; Age (years): 64; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA, RIGHT LOWER LET	2020-10-02 (22)/ 2020-10-02 (22)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA, RIGHT SCAPULAR ARCH	2020-10-02 (22)/ 2020-10-02 (22)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282072; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 (7)/ 2020-08-28 (8)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3282085; Age (years): 78; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-31 (6)/ 2020-09-07 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Bone contusion/ BRUISED TAILBONE	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT HIP PAIN	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282115; Age (years): 36; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Breast mass/ RIGHT BREAST LUMP	2020-11-02 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292017; Age (years): 66; Sex: F; Race: WHITE							
Renal and urinary disorders/ Urinary incontinence/ URINARY INCONTINENCE	2020-08-17 (14)/ 2020-08-17 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292029; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Staphylococcal infection/ STAPH INFECTION	2020-09-15 (15)/ 2020-10-02 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292053; Age (years): 45; Sex: M; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-09-30 (26)/ 2020-10-09 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292058; Age (years): 32; Sex: F; Race: WHITE							
Infections and infestations/ Conjunctivitis bacterial/ BILATERAL BACTERIAL CONJUNCTIVITIS	2020-10-01 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292075; Age (years): 25; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-19 (47)/ 2020-10-28 (56)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-23 (51)/ 2020-10-23 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-26 (54)/ 2020-10-26 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292085; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ Breast abscess/ ABSCESS ON LEFT BREAST	2020-09-18 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292115; Age (years): 45; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Non-cardiac chest pain/ CHEST PAIN (NON-CARDIAC)	2020-09-25 (18)/ 2020-09-26 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292155; Age (years): 78; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE	2020-08-23 (11)/ 2020-09-04 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292159; Age (years): 71; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-21 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3292159; Age (years): 71; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-08-21 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292196; Age (years): 38; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ FRACTURED TOOTH #18	2020-11-04 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292227; Age (years): 54; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Joint injury/ ANKLE INJURY	2020-11-05 (52)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292229; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-23 (6)/ 2020-09-01 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3292236; Age (years): 80; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-09-03 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Fibromuscular dysplasia/ FIBROMUSCULAR DYSPLASIA	2020-09-04 (16)/ 2020-09-05 (17)	Yes/ Yes/ No	2	Yes/3 (2020-09-04/ 2020-09-05)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292248; Age (years): 47; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Impaired gastric emptying/ EXACERBATION OF GASTROPARESIS	2020-09-10 (22)/ 2020-09-14 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292259; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Eye infection/ EYE INFECTION	2020-08-30 (11)/ 2020-09-17 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3292259; Age (years): 50; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-07 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-11-07 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-07 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-07 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292259; Age (years): 50; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-07 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHES	2020-11-07 (52)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-16 (61)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-11-16 (61)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3292259; Age (years): 50; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-16 (61)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-11-16 (61)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-16 (61)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292259; Age (years): 50; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-16 (61)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-16 (61)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292261; Age (years): 71; Sex: M; Race: WHITE							
Eye disorders/ Dry eye/ CHRONIC DRY EYES	2020-10-14 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292270; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ Fungal infection/ FUNGAL INFECTION	2020-09-05 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292270; Age (years): 34; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Iron deficiency anaemia/ IRON DEFICIENCY ANEMIA	2020-09-16 (27)/ 2020-10-08 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292271; Age (years): 58; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 (1)/ 2020-10-17 (29)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-15 (27)/ 2020-10-16 (28)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-15 (27)/ 2020-10-21 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292271; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-15 (27)/ 2020-10-21 (33)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-16 (28)/ 2020-10-21 (33)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292289; Age (years): 37; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC POSITIVE COVID-19	2020-10-31 (40)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292292; Age (years): 73; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-01 (41)/ 2020-11-05 (45)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHES	2020-11-01 (41)/ 2020-11-07 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-01 (41)/ 2020-11-07 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-11-01 (41)/ 2020-11-07 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292297; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Tinea pedis/ TINEA PEDIS	2020-09-11 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292307; Age (years): 37; Sex: F; Race: WHITE							
Investigations/ Blood prolactin increased/ ELEVATED PROLACTIN LEVELS	2020-10-05 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292320; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Cartilage injury/ LEFT HIP LABRUM TEAR	2020-08-27 (3)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-30/ 2020-09-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Injury, poisoning and procedural complications/ Iliotibial band syndrome/ ILIOTIBIAL BAND SYNDROME	2020-08-30 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292320; Age (years): 54; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bursitis/ TROCHANTERIC BURSITIS	2020-08-30 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ BILATERAL HIP OSTEOARTHRITIS	2020-08-30 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Musculoskeletal and connective tissue disorders/ Vertebral foraminal stenosis/ FORAMINAL STENOSIS L4/L5	2020-08-30 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292320; Age (years): 54; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	2020-08-30 (6)/ 2020-09-04 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	2020-08-30 (6)/ 2020-09-04 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ POSITIVE SYMPTOMATIC COVID-19	2020-11-15 (55)/ Ongoing	Yes/ Yes/ No	2	No		/ NONE	
Subject ID: US3292339; Age (years): 70; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Angioedema/ ANGIOEDEMA	2020-09-16 (21)/ 2020-09-18 (23)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-17/ 2020-09-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292339; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-01 (1)/ 2020-10-20 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292343; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-10-24 (31)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292375; Age (years): 54; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH ON FACE ALL THE WAY TO MID-TORSO	2020-09-19 (22)/ 2020-09-19 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-11-05 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292375; Age (years): 54; Sex: F; Race: WHITE							
Vascular disorders/ Ischaemia/ ISCHEMIA	2020-11-05 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-11-13 (49)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Localised infection/ INFECTION ON RIGHT ARM	2020-11-20 (56)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292395; Age (years): 42; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 POSITIVE	2020-11-07 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292407; Age (years): 48; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 TEST POSITIVE	2020-10-27 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292427; Age (years): 45; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Influenza like illness/ FLU-LIKE SYMPTOMS	2020-11-07 (6)/ 2020-11-12 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292436; Age (years): 43; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Food poisoning/ FOOD POISONING	2020-11-07 (10)/ 2020-11-12 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3302021; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Systemic lupus erythematosus/ LUPUS	2020-11-10 (72)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302065; Age (years): 67; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-11-11 (71)/ 2020-11-15 (75)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-12 (72)/ 2020-11-15 (75)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3302069; Age (years): 57; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dyspepsia/ INDIGESTION	2020-11-18 (77)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	2020-11-18 (77)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302069; Age (years): 57; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ DRY COUGH	2020-11-18 (77)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-18 (77)/ 2020-11-24 (83)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-18 (77)/ 2020-11-24 (83)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-11-22 (81)/ 2020-11-24 (83)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302078; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-20 (48)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3302112; Age (years): 73; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENED HYPERTENSION	2020-09-10 10:35 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3302137; Age (years): 67; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-11-12 (50)/ 2020-11-18 (56)	Yes/ Yes/ No	1	No	NA/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ NASAL / CHEST CONGESTION	2020-11-12 (50)/ 2020-11-23 (61)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302161; Age (years): 63; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-26 (48)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-27 (49)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-27 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-27 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302221; Age (years): 51; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS	2020-10-22 (42)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3302275; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-10-20 (35)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3302283; Age (years): 63; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-05 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3302295; Age (years): 31; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-09-21 (1)/ 2020-10-19 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302333; Age (years): 50; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES- LEGS	2020-10-10 (20)/ 2020-10-17 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3302383; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-22 (28)/ 2020-09-29 (35)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE RESPIRATORY FAILURE	2020-09-26 (32)/ 2020-09-28 (34)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-28)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302432; Age (years): 30; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-11-06 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Hypertension/ HIGH BLOOD PRESSURE	2020-11-06 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3302466; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-09 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3302470; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHES	2020-11-11 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312004; Age (years): 31; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-13 (37)/ 2020-10-16 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-16 (40)/ 2020-10-16 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-16 (40)/ 2020-10-19 (43)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-16 (40)/ 2020-10-20 (44)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312004; Age (years): 31; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-16 (40)/ 2020-10-26 (50)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-20 (44)/ 2020-10-26 (50)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-21 (45)/ 2020-10-21 (45)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-22 (46)/ 2020-10-26 (50)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312005; Age (years): 45; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-26 (50)/ 2020-10-30 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-26 (50)/ 2020-11-01 (56)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-29 (53)/ 2020-10-29 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312028; Age (years): 72; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-19 (13)/ 2020-09-22 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312035; Age (years): 27; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-08-21 (11)/ 2020-08-28 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312053; Age (years): 20; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-02 (24)/ 2020-10-03 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-02 (24)/ 2020-10-07 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-04 (26)/ 2020-10-07 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312053; Age (years): 20; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-10-05 (27)/ 2020-10-07 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312060; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-09-12 (3)/ 2020-09-22 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312064; Age (years): 67; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-10-26 (47)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312068; Age (years): 21; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-08-17 (5)/ 2020-08-28 (16)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312075; Age (years): 20; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-26 (12)/ 2020-09-29 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312086; Age (years): 51; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-07 (58)/ 2020-11-07 (58)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS ENTEROVIRUS	2020-11-10 (61)/ 2020-11-12 (63)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312093; Age (years): 57; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Corneal abrasion/ LEFT CORNEAL ABRASION	2020-09-09 (27)/ 2020-09-16 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312101; Age (years): 32; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-20 (37)/ 2020-10-21 (38)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-10-21 (38)/ 2020-10-23 (40)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-21 (38)/ 2020-10-23 (40)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312101; Age (years): 32; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-21 (38)/ 2020-10-23 (40)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-21 (38)/ 2020-10-23 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312113; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-19 (34)/ 2020-10-19 (34)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312113; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-19 (34)/ 2020-10-19 (34)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-19 (34)/ 2020-10-19 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-19 (34)/ 2020-10-20 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-19 (34)/ 2020-10-21 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312113; Age (years): 49; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-19 (34)/ 2020-10-25 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-19 (34)/ 2020-10-25 (40)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-10-22 (37)/ 2020-10-25 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312140; Age (years): 22; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-03 (51)/ 2020-11-06 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312140; Age (years): 22; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-03 (51)/ 2020-11-10 (58)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-03 (51)/ 2020-11-10 (58)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-11-03 (51)/ 2020-11-10 (58)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312140; Age (years): 22; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-03 (51)/ 2020-11-13 (61)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-09 (57)/ 2020-11-13 (61)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312149; Age (years): 77; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-28 (13)/ 2020-10-08 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-02 (17)/ 2020-10-08 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312149; Age (years): 77; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-02 (17)/ 2020-10-09 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-11 (26)/ 2020-10-13 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312165; Age (years): 43; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-30 (15)/ 2020-10-02 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-30 (15)/ 2020-10-05 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312165; Age (years): 43; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-30 (15)/ 2020-11-18 (64)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-01 (16)/ 2020-10-02 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312168; Age (years): 32; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-11 (26)/ 2020-10-16 (31)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312168; Age (years): 32; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-11 (26)/ 2020-10-17 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-11 (26)/ 2020-10-18 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-11 (26)/ 2020-10-24 (39)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-12 (27)/ 2020-10-12 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312168; Age (years): 32; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 (30)/ 2020-10-15 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 (30)/ 2020-10-16 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312171; Age (years): 50; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-17 (32)/ 2020-10-17 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-17 (32)/ 2020-10-18 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312171; Age (years): 50; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-17 (32)/ 2020-10-18 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-17 (32)/ 2020-10-20 (35)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-17 (32)/ 2020-10-20 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312171; Age (years): 50; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-17 (32)/ 2020-10-25 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-18 (33)/ 2020-10-19 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312185; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-11-14 (59)/ 2020-11-24 (69)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-14 (59)/ 2020-11-24 (69)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312187; Age (years): 31; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rhabdomyolysis/ RHABDOMYOLISIS	2020-11-08 (53)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-12/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3312198; Age (years): 83; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-21 (5)/ 2020-09-28 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312199; Age (years): 22; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-19 (3)/ 2020-09-26 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312199; Age (years): 22; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-19 (3)/ 2020-09-27 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312201; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-08-24 (5)/ 2020-10-09 (51)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Large intestine polyp/ COLONIC POLYP	2020-10-09 (51)/ 2020-10-09 (51)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3312210; Age (years): 50; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-04 (48)/ 2020-11-08 (52)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312210; Age (years): 50; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-11-05 (49)/ 2020-11-06 (50)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-05 (49)/ 2020-11-06 (50)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-11-06 (50)/ 2020-11-06 (50)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-06 (50)/ 2020-11-08 (52)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312210; Age (years): 50; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-08 (52)/ 2020-11-12 (56)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-10 (54)/ 2020-11-10 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312212; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ HERPES ZOSTER	2020-08-28 (8)/ 2020-11-06 (78)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312212; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Osteomyelitis/ LEFT GREAT TOE OSTEOMYELITIS	2020-09-04 (15)/ 2020-10-16 (57)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-09)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: RECOVERED WITH SEQUALAE LEFT GREAT TOE AMPUTATION
Subject ID: US3312225; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-04 (45)/ 2020-11-17 (58)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312235; Age (years): 35; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT FOOT SPRAIN	2020-09-18 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-08 (49)/ 2020-11-13 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312236; Age (years): 65; Sex: F; Race: WHITE							
Eye disorders/ Ulcerative keratitis/ DEEP CENTER CORNEAL ULCER LEFT EYE	2020-10-06 (16)/ 2020-10-12 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312244; Age (years): 46; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Uterine cyst/ BENIGN UTERINE FIBROID CYSTS	2020-09-14 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312256; Age (years): 52; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ TOP LEFT BROKEN MOLAR	2020-09-16 (23)/ 2020-09-22 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3312258; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ INJECTION SITE BRUISE	2020-09-23 (2)/ 2020-10-11 (20)	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312273; Age (years): 25; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT IPSILATERAL AXILLARY LYMPHADENOPATHY	2020-09-22 (1)/ 2020-09-24 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312284; Age (years): 22; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-15 (55)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312289; Age (years): 68; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-05 (37)/ 2020-11-07 (39)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-05 (37)/ 2020-11-08 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312289; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-05 (37)/ 2020-11-08 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-05 (37)/ 2020-11-08 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312291; Age (years): 63; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-30 (38)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-30 (38)/ 2020-11-04 (43)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312291; Age (years): 63; Sex: F; Race: WHITE							
Investigations/ Blood pressure diastolic increased/ ELEVATED DIASTOLIC BLOOD PRESSURE CAUSES	2020-11-02 (41)/ 2020-11-12 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-11-02 (41)/ 2020-11-12 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-03 (42)/ 2020-11-04 (43)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
			1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312291; Age (years): 63; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-10 (49)/ 2020-11-10 (49)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312296; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-26 (34)/ 2020-11-24 (63)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312302; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Otitis externa/ LEFT OTITIS EXTERNA	2020-09-21 (27)/ 2020-09-25 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312312; Age (years): 40; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-06 (12)/ 2020-09-11 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312312; Age (years): 40; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-06 (12)/ 2020-09-11 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIAS	2020-09-06 (12)/ 2020-09-11 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-06 (12)/ 2020-09-14 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-08 (14)/ 2020-09-11 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312312; Age (years): 40; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Blood and lymphatic system disorders/ Lymphadenopathy/ BILATERAL CERVICAL LYMPHADENOPATHY	2020-09-10 (16)/ 2020-09-22 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312325; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-31 (38)/ 2020-11-02 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312331; Age (years): 76; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ RIGHT MAXILLARY PAIN RELATED TO DENTAL PROCEDURES	2020-09-14 (19)/ 2020-09-18 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312354; Age (years): 63; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-26 (35)/ 2020-10-30 (39)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-30 (39)/ 2020-10-30 (39)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-30 (39)/ 2020-10-30 (39)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312354; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-30 (39)/ 2020-10-30 (39)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-30 (39)/ 2020-10-31 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNYNOSE	2020-10-30 (39)/ 2020-10-31 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312354; Age (years): 63; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-30 (39)/ 2020-11-01 (41)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312390; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-06 (7)/ 2020-09-12 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312393; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ LUMBAR STRAIN	2020-09-12 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312395; Age (years): 55; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ CERVICALGIA	2020-09-12 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312398; Age (years): 47; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-28 (31)/ 2020-10-31 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-28 (31)/ 2020-11-03 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-02 (36)/ 2020-11-02 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312402; Age (years): 19; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-22 (25)/ 2020-10-28 (31)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312413; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-02 (3)/ 2020-09-04 (5)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-02 (3)/ 2020-09-04 (5)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIAS	2020-09-02 (3)/ 2020-09-06 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312413; Age (years): 50; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-02 (3)/ 2020-09-06 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-03 (4)/ 2020-09-04 (5)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312415; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-16 (17)/ 2020-09-22 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312456; Age (years): 59; Sex: M; Race: WHITE							
Cardiac disorders/ Ventricular extrasystoles/ PREMATURE VENTRICULAR CONTRACTIONS	2020-09-02 (1)/ 2020-09-30 10:04 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312464; Age (years): 24; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-05 (4)/ 2020-09-09 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312493; Age (years): 46; Sex: F; Race: MULTIPLE: (b) (6)							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-27 (25)/ 2020-10-05 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-27 (25)/ 2020-10-07 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312501; Age (years): 39; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-31 (30)/ 2020-11-03 (33)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312501; Age (years): 39; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-31 (30)/ 2020-11-05 (35)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-31 (30)/ 2020-11-05 (35)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-01 (31)/ 2020-11-02 (32)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-02 (32)/ 2020-11-02 (32)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312501; Age (years): 39; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-02 (32)/ 2020-11-05 (35)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-04 (34)/ 2020-11-05 (35)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-05 (35)/ 2020-11-05 (35)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-05 (35)/ 2020-11-05 (35)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312527; Age (years): 44; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-21 (14)/ 2020-09-24 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-22 (15)/ 2020-09-24 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Muscle strain/ BACK MUSCLE STRAIN	2020-10-15 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312535; Age (years): 47; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-26 (21)/ 2020-10-26 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312535; Age (years): 47; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-10-26 (21)/ 2020-10-26 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-28 (23)/ 2020-10-30 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312539; Age (years): 66; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ RIGHT INDEX FINGER LACERATION	2020-10-13 (8)/ 2020-10-18 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312548; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-03 (26)/ 2020-10-15 (38)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312548; Age (years): 65; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-10-07 (30)/ 2020-11-03 (57)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312558; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-11 (5)/ 2020-10-12 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-11 (5)/ 2020-10-12 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-11 (5)/ 2020-10-12 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312558; Age (years): 51; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-11 (5)/ 2020-10-12 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-11 (5)/ 2020-10-12 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-11 (5)/ 2020-10-12 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-11 (5)/ 2020-10-14 (8)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312558; Age (years): 51; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-11 (5)/ 2020-10-14 (8)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-13 (7)/ 2020-10-23 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312587; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-03 (25)/ 2020-10-20 (42)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312592; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-28 (21)/ 2020-10-28 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312592; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-28 (21)/ 2020-10-28 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-28 (21)/ 2020-10-28 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-28 (21)/ 2020-10-28 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312592; Age (years): 63; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-28 (21)/ 2020-10-28 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312605; Age (years): 24; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-19 (12)/ 2020-11-02 (26)	Yes/ Yes/ No	3	Yes/3 (2020-10-27/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312622; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-19 (11)/ 2020-11-14 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312623; Age (years): 31; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-06 (26)/ 2020-10-08 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312623; Age (years): 31; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-06 (26)/ 2020-10-08 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-06 (26)/ 2020-10-08 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-10 (30)/ 2020-10-10 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312626; Age (years): 47; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-09-15 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312626; Age (years): 47; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in jaw/ JAW PAIN	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312627; Age (years): 49; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-09-30 (20)/ 2020-10-09 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312629; Age (years): 53; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Epicondylitis/ LEFT TENNIS ELBOW (LATERAL EPICONDYLITIS)	2020-10-15 (3)/ 2020-11-06 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2020-11-06 (25)/ 2020-11-10 (29)	Yes/ Yes/ No	3	Yes/3 (2020-11-06/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322003; Age (years): 51; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-04 (22)/ 2020-09-10 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-21 (39)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Infections and infestations/ Tooth infection/ DENTAL INFECTION	2020-09-25 (43)/ 2020-10-02 (50)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322006; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-09-09 (24)/ 2020-10-06 (51)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322006; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	2020-09-28 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3322013; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-08-17 14:00 (1)/ 2020-08-17 14:03 (1)	No/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3322036; Age (years): 28; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-26 (6)/ 2020-10-06 (16)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-29 (9)/ 2020-10-06 (16)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322053; Age (years): 49; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-23 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3322056; Age (years): 20; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-19 (2)/ 2020-09-22 (5)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3322061; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-09-07 (18)/ 2020-09-15 (26)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322064; Age (years): 46; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Tinnitus/ TINNITUS	2020-10-03 (11)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322076; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-18 (2)/ 2020-10-02 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322086; Age (years): 56; Sex: M; Race: ASIAN							
Infections and infestations/ Pharyngitis/ PHARYNGITIS, ACUTE	2020-10-04 (10)/ 2020-10-10 (16)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322087; Age (years): 55; Sex: F; Race: ASIAN							
Infections and infestations/ Tonsillitis/ TONSILLITIS	2020-09-11 (18)/ 2020-09-12 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-25 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322087; Age (years): 55; Sex: F; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIA	2020-09-25 (1)/ 2020-10-04 (10)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Middle ear effusion/ SEROUS FLUID BEHIND LEFT TYMPANIC MEMBRANE	2020-10-07 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3322095; Age (years): 36; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES, LEFT	2020-10-01 (9)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322111; Age (years): 66; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ PERSISTED ELEVATED BLOOD PRESSURE	2020-08-26 16:15 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322119; Age (years): 47; Sex: F; Race: WHITE							
Immune system disorders/ Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2020-09-12 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3322139; Age (years): 40; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Gout/ GOUT	2020-09-18 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Syphilis/ SYPHILIS	2020-09-25 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322159; Age (years): 68; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Joint injury/ LEFT KNEE INJURY	2020-10-19 (6)/ 2020-10-19 (6)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322189; Age (years): 62; Sex: F; Race: WHITE							
Renal and urinary disorders/ Bladder prolapse/ WORSENING URINARY BLADDER PROLAPSE	2020-10-06 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3322195; Age (years): 55; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-19 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-19 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322199; Age (years): 64; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Myocardial infarction/ FATAL MYOCARDIAL INFARCTION	2020-11-16 (47)/ 2020-11-16 (47)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ NONE	FATAL

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322239; Age (years): 27; Sex: M; Race: ASIAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-10-22 (14)/ 2020-10-27 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322240; Age (years): 29; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-11-16 (42)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3322303; Age (years): 39; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-09-18 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322327; Age (years): 36; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-25 (14)/ 2020-10-01 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322345; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-09-24 (11)/ 2020-10-03 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3322347; Age (years): 44; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-23 (11)/ 2020-10-26 (14)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322362; Age (years): 42; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 (1)/ 2020-10-12 (26)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Viral upper respiratory tract infection/ UPPER RESPIRATORY INFECTION, HUMAN RHINOVIRUS/ENTEROVIRUS	2020-10-07 (21)/ 2020-10-25 (39)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322377; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ Gastroenteritis/ ACUTE GASTROENTERITIS	2020-09-29 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3322381; Age (years): 24; Sex: M; Race: ASIAN							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-11-13 (26)/ Ongoing	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3322405; Age (years): 27; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-08 (7)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322409; Age (years): 31; Sex: F; Race: ASIAN							
Infections and infestations/ Herpes zoster/ SHINGLES - LEFT FOOT/ANKLE	2020-10-11 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322409; Age (years): 31; Sex: F; Race: ASIAN							
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE (LEFT/RIGHT THIGH)	2020-10-23 (22)/ 2020-10-23 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-07 (3)/ 2020-11-14 (10)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322420; Age (years): 43; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Skin laceration/ FINGER LACERATION, SECOND FINGER RIGHT HAND	2020-10-11 (4)/ 2020-10-11 (4)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Localised infection/ INFECTION ON RIGHT INDEX FINGER	2020-10-13 (6)/ 2020-10-25 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332001; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-30 (34)/ 2020-10-02 (36)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS ETIOLOGY UNKNOWN	2020-10-02 (36)/ 2020-10-20 (54)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-11-17 (82)/ 2020-11-17 (82)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332005; Age (years): 71; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Rib fracture/ LEFT CRACKED RIBS#7 AND #8	2020-11-19 (81)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3332017; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-08-23 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3332024; Age (years): 35; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-05 (30)/ 2020-09-05 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332024; Age (years): 35; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Nervous system disorders/ Nerve compression/ RIGHT ULNAR PINCHED NERVE	2020-09-05 (30)/ 2020-09-06 (31)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332030; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Cystitis/ BLADDER INFECTION	2020-09-02 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3332035; Age (years): 31; Sex: F; Race: WHITE							
Eye disorders/ Macular degeneration/ LEFT EYE MACULAR DEGENERATION	2020-10-01 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3332038; Age (years): 73; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ FLU VACCINE SITE REACTION- SORENESS AT INJECTION SITE	2020-10-18 (34)/ 2020-10-22 (38)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3332042; Age (years): 44; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 (3)/ 2020-09-22 (8)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3332058; Age (years): 46; Sex: F; Race: WHITE							
Hepatobiliary disorders/ Hepatic cyst/ WORSENING OF LIVER CYSTS	2020-10-13 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Haemangioma of liver/ WORSENING OF LIVER HEMANGIOMAS	2020-10-13 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Reproductive system and breast disorders/ Ovarian cyst/ BILATERAL OVARIAN CYSTS	2020-10-13 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332058; Age (years): 46; Sex: F; Race: WHITE							
Investigations/ Heart rate irregular/ SENSATION OF ERRACTIC PULSE	2020-11-05 (46)/ 2020-11-05 (46)	Yes/ Yes/ No	4	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342010; Age (years): 24; Sex: M; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT HYPERACTIVITY DISORDER.	2020-10-30 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342019; Age (years): 23; Sex: F; Race: WHITE							
Infections and infestations/ Viral upper respiratory tract infection/ VIRAL URI	2020-11-20 (74)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342023; Age (years): 69; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Meniscus injury/ RIGHT MENISCAL TEAR	2020-09-23 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342031; Age (years): 22; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS (BILATERAL AXILLARY)	2020-09-12 (33)/ 2020-09-15 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342032; Age (years): 28; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-06 (22)/ 2020-10-10 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	2020-10-06 (22)/ 2020-10-10 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-06 (22)/ 2020-10-10 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342042; Age (years): 63; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Burns second degree/ 2ND DEGREE BURN RIGHT FOOT	2020-08-20 (9)/ 2020-09-15 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342043; Age (years): 66; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPAL EPISODE	2020-08-25 (14)/ 2020-08-25 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342046; Age (years): 41; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19 INFECTION	2020-11-17 (63)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342051; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ Infected dermal cyst/ INFECTED SEBACEOUS CYST LEFT BUTTOCKS	2020-10-27 (44)/ 2020-11-02 (50)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3342056; Age (years): 22; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis/ IDIOPATHIC PHARYNGITIS	2020-08-31 (19)/ 2020-09-05 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342085; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Viral upper respiratory tract infection/ VIRAL UPPER RESPIRATORY INFECTION	2020-11-13 (59)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342087; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ Gastroenteritis viral/ PROBABLE VIRAL GASTROENTERITIS	2020-08-29 (13)/ 2020-08-30 (14)	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342088; Age (years): 50; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Colon cancer stage III/ STAGE III COLON CANCER	2020-09-15 (30)/ Ongoing	Yes/ Yes/ No	2	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342093; Age (years): 53; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Stress fracture/ LEFT FOOT STRESS FRACTURE	2020-08-20 (3)/ 2020-09-24 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342103; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Soft tissue infection/ SOFT TISSUE INFECTION OF LEFT HAND	2020-09-06 (20)/ 2020-09-18 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342128; Age (years): 40; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Intervertebral disc degeneration/ DEGENERATIVE DISC DISEASE	2020-08-27 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342130; Age (years): 72; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Skin cancer/ NONMELANOMA SKIN CANCER ON BRIDGE OF NOSE	2020-08-28 (9)/ 2020-10-08 (50)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342130; Age (years): 72; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Bone contusion/ LEFT SIDED RIB CONTUSION	2020-08-30 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3342132; Age (years): 47; Sex: M; Race: WHITE							
Infections and infestations/ Tinea pedis/ TINEA PEDIS (LEFT FOOT)	2020-09-10 (22)/ 2020-10-02 (44)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342146; Age (years): 33; Sex: F; Race: WHITE							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-09-04 (10)/ 2020-09-14 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-09-16 (22)/ 2020-09-22 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342146; Age (years): 33; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-09-24 (30)/ 2020-09-25 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Pharyngitis/ MILD PHARYNGITIS	2020-09-24 (30)/ 2020-09-25 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-10 (47)/ 2020-11-13 (50)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342157; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-11-17 (47)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342168; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Paronychia/ PARONYCHIA RIGHT GREAT TOE	2020-09-03 00:00 (1)/ 2020-09-03 12:00 (2)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3342170; Age (years): 56; Sex: M; Race: WHITE							
Investigations/ Blood testosterone decreased/ LOW TESTOSTERONE	2020-11-06 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342177; Age (years): 73; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin lesion/ SKIN LESION ON NASOLABIAL FOLD	2020-10-23 (26)/ 2020-10-23 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3342182; Age (years): 70; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ MEDICATION INDUCED HEADACHE	2020-09-18 (16)/ 2020-10-28 (56)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342182; Age (years): 70; Sex: F; Race: WHITE							
Psychiatric disorders/ Generalised anxiety disorder/ GENERALIZED ANXIETY	2020-10-26 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3342184; Age (years): 54; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ THROAT IRRITATION	2020-09-03 15:33 (1)/ 2020-09-03 15:44 (1)	Yes/ Yes/ No	1	No	NR/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Vertigo positional/ BENIGN PAROXYSMAL POSITIONAL VERTIGO	2020-11-13 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3342186; Age (years): 39; Sex: F; Race: WHITE							
Psychiatric disorders/ Generalised anxiety disorder/ WORSENING OF GENERALIZED ANXIETY DISORDER	2020-09-24 (22)/ 2020-10-15 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342195; Age (years): 72; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-14 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Mass/ MASS RIGHT ATRIUM	2020-10-18 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342196; Age (years): 81; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ HERNIATED DISC L4	2020-10-15 (42)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342199; Age (years): 59; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Colitis/ ACUTE FOCAL COLITIS	2020-09-13 (10)/ 2020-09-25 (22)	Yes/ Yes/ No	3	Yes/3 (2020-09-13/ 2020-09-15)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342200; Age (years): 44; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Intraductal proliferative breast lesion/ DUCTAL CARCINOMA IN SITU RIGHT BREAST	2020-11-20 (52)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342201; Age (years): 73; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperuricaemia/ ASYMPTOMATIC HYPERURICEMIA	2020-09-25 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342213; Age (years): 31; Sex: M; Race: ASIAN							
Infections and infestations/ Pharyngitis/ ACUTE PHARYNGITIS	2020-10-07 (29)/ 2020-10-19 (41)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342229; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Presyncope/ VASOVAGAL REACTION TO SEEING HER OWN BLOOD	2020-09-10 11:40 (1)/ 2020-09-10 11:50 (1)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Psychiatric disorders/ Anxiety/ EXACERBATION OF ANXIETY	2020-10-06 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3342253; Age (years): 24; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pleurisy/ IDIOPATHIC PLEURISY RECURRENCE	2020-09-18 (8)/ 2020-10-19 (39)	Yes/ Yes/ No	2	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342256; Age (years): 43; Sex: M; Race: UNKNOWN							
Cardiac disorders/ Cardio-respiratory arrest/ CARDIOPULMONARY ARREST	2020-09-20 (7)/ 2020-09-20 (7)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	FATAL

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Subject ID: US3342259; Age (years): 41; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression suicidal/ DEPRESSION WITH SUICIDAL IDEATION	2020-10-14 (31)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342273; Age (years): 25; Sex: M; Race: WHITE							
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-10-19 (32)/ 2020-10-20 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHES	2020-10-19 (32)/ 2020-10-20 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342276; Age (years): 47; Sex: M; Race: WHITE							
Congenital, familial and genetic disorders/ Hydrocele/ HYDROCELE (L) TESTICLE	2020-10-28 (8)/ 2020-10-31 (11)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342295; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ ACUTE VIRAL ILLNESS	2020-10-14 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3342297; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-13 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Angina pectoris/ ANGINA	2020-10-19 (21)/ 2020-10-19 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342301; Age (years): 23; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression/ EXACERBATION OF DEPRESSION	2020-10-07 (8)/ 2020-10-28 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342323; Age (years): 26; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-11 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3342328; Age (years): 37; Sex: F; Race: WHITE							
Immune system disorders/ Hypersensitivity/ ALLERGEN	2020-11-23 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342336; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-11-23 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3342337; Age (years): 31; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Fibromyalgia/ FIBROMYALGIA EXACERBATION	2020-10-19 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342343; Age (years): 61; Sex: F; Race: UNKNOWN							
Infections and infestations/ Viral infection/ ACUTE VIRAL INFECTION-FATIGUE, MUSCLE ACHES, HEADACHE	2020-10-18 (7)/ 2020-10-27 (16)	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Intervertebral disc disorder/ WORSENING OF CERVICAL DISC DISEASE	2020-10-19 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Synovitis/ NEW ONSET OF SYMMETRICAL SYNOVITIS OF HANDS AND FEET	2020-10-26 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352033; Age (years): 61; Sex: M; Race: WHITE							
Cardiac disorders/ Acute myocardial infarction/ ACUTE INFERIOR WALL MYOCARDIAL INFARCTION	2020-11-05 (57)/ 2020-11-05 (57)	Yes/ Yes/ No	4	Yes/3 (2020-11-05/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352072; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-08-19 (7)/ 2020-09-04 (23)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352090; Age (years): 35; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-05 (59)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3352095; Age (years): 63; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ GRADE 3 INCREASED SYSTOLIC BLOOD PRESSURE	2020-08-13 18:01 (1)/ 2020-09-08 14:53 (26)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352099; Age (years): 30; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Palatal oedema/ UVULA EDEMA	2020-10-13 (27)/ 2020-10-18 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352383; Age (years): 59; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ BACK SPASM	2020-10-07 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3352390; Age (years): 80; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Food poisoning/ FOOD POISONING	2020-10-08 (20)/ 2020-10-11 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352424; Age (years): 53; Sex: M; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-10-05 (12)/ 2020-10-18 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352424; Age (years): 53; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-05 (12)/ 2020-10-18 (25)	Yes/ Yes/ No	3	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
			4	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	2020-10-17 (24)/ 2020-10-18 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	2020-10-17 (24)/ 2020-10-18 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352581; Age (years): 34; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-10-26 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3362001; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-08-13 (14)/ 2020-08-20 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362004; Age (years): 46; Sex: M; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID 19	2020-08-07 (7)/ 2020-08-08 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362012; Age (years): 42; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-05 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362018; Age (years): 46; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-22 (53)/ 2020-11-02 (64)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-11-02 (64)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362021; Age (years): 25; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-08-14 (12)/ 2020-08-24 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-08-14 (12)/ 2020-08-24 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362026; Age (years): 62; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-22 (23)/ 2020-10-01 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-25 (26)/ 2020-10-01 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 (26)/ 2020-10-01 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362029; Age (years): 52; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-17 (14)/ 2020-08-20 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362038; Age (years): 29; Sex: F; Race: WHITE							
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	2020-10-21 (31)/ 2020-10-21 (31)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362041; Age (years): 37; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-10-05 (32)/ 2020-10-27 (54)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362042; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-07 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362055; Age (years): 42; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-22 (15)/ 2020-09-24 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362058; Age (years): 43; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ DENTAL CARIES	2020-08-18 (13)/ 2020-08-18 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3362083; Age (years): 18; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-08-28 (21)/ 2020-09-06 (30)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362094; Age (years): 40; Sex: M; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ COVID 19 STYMPTOMS	2020-11-06 (47)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362101; Age (years): 42; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-10 (32)/ 2020-09-11 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362101; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-10 (32)/ 2020-09-15 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362106; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-19 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3362110; Age (years): 49; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-15 00:00 (1)/ 2020-09-24 00:00 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-15 00:00 (1)/ 2020-09-24 00:00 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362118; Age (years): 52; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-10-02 (19)/ 2020-10-09 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362125; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-08 (55)/ 2020-11-13 (60)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362156; Age (years): 32; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP PHARYNGITIS	2020-10-13 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362175; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ Pelvic abscess/ SUPRAPUBIC ABSCESS	2020-08-18 (2)/ 2020-08-24 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362184; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-08-18 07:00 (1)/ 2020-08-24 00:00 (7)	No/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-09-19 (33)/ 2020-09-30 (44)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362193; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-02 (29)/ 2020-10-06 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362196; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID 19	2020-09-20 (32)/ 2020-09-25 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362200; Age (years): 65; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-21 (2)/ 2020-10-15 (57)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362208; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-18 (30)/ 2020-09-20 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	2020-09-19 (31)/ 2020-09-26 (38)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-09-22 (34)/ 2020-10-01 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362208; Age (years): 59; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-26 (25)/ 2020-10-28 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362266; Age (years): 70; Sex: F; Race: WHITE							
Psychiatric disorders/ Adjustment disorder with depressed mood/ BEREAVEMENT WITH DEPRESSION	2020-09-16 (17)/ 2020-10-26 (57)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362273; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-10 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362273; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod sting/ BEE STING RIGHT HAND 5TH DIGIT	2020-10-17 (16)/ 2020-10-19 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-18 (17)/ 2020-10-19 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362297; Age (years): 22; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-16 (16)/ 2020-10-27 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362306; Age (years): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-12 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362315; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-16 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362321; Age (years): 35; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Cervical dysplasia/ CERVICAL DYSPLASIA	2020-10-26 (4)/ 2020-11-06 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3372005; Age (years): 94; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-08-25 (22)/ 2020-08-25 (22)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372023; Age (years): 61; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-10-31 (61)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372046; Age (years): 60; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-08-13 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372060; Age (years): 60; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	2020-08-17 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372068; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-12 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372075; Age (years): 79; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Cyst/ BENIGN CYST- BACK	2020-11-05 (56)/ 2020-11-05 (56)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372078; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bone lesion/ LESION RIGHT MANDIBLE	2020-10-01 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Product issues/ Device physical property issue/ SHATTERED IMPLANT RIGHT UPPER MOLAR	2020-10-01 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL CARCINOMA RIGHT MANDIBLE	2020-10-22 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372089; Age (years): 74; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA - RIGHT SHOULDER LATERAL.	2020-08-18 (8)/ 2020-09-08 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL CARCINOMA - LEFT UPPER ARM LATERAL.	2020-08-18 (8)/ 2020-09-08 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3372110; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-04 (23)/ 2020-09-08 (27)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372110; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Acute sinusitis/ ACUTE SINUSITIS	2020-09-04 (23)/ 2020-09-10 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372117; Age (years): 72; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Exostosis/ BONE SPUR L4-L5	2020-10-26 (42)/ 2020-10-26 (42)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372121; Age (years): 68; Sex: F; Race: WHITE							
Nervous system disorders/ Neuralgia/ RIGHT HAND NERVE PAIN	2020-08-27 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372126; Age (years): 71; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin abrasion/ ABRASION LEFT FOREARM	2020-10-09 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372126; Age (years): 71; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin abrasion/ ABRASION LEFT LOWER LEG	2020-10-09 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Skin abrasion/ ABRASION RIGHT FOREARM	2020-10-09 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Skin abrasion/ ABRASION RIGHT LOWER LEG	2020-10-09 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372129; Age (years): 55; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermal cyst/ SEBACEOUS CYST UPPER BACK - LEFT UPPER BACK	2020-08-25 (12)/ 2020-09-10 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372149; Age (years): 65; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE	2020-10-20 (35)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372184; Age (years): 72; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain lower/ RIGHT LOWER ABDOMINAL PAIN	2020-08-28 (10)/ 2020-08-28 (10)	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372193; Age (years): 65; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Clavicle fracture/ LEFT CLAVICLE FRACTURE	2020-09-18 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Rash macular/ RASH FROM SLING IN THE LEFT ARM-MACULAR NON-URTICARIAL	2020-09-19 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372229; Age (years): 34; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ HYPEREMESIS	2020-10-30 (68)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-30 (68)/ 2020-10-30 (68)	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372237; Age (years): 23; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-05 (45)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372243; Age (years): 76; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Periorbital haemorrhage/ LEFT INFRAORBITAL EQUIMOSIS	2020-09-23 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372243; Age (years): 76; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Lip injury/ UPPER LIP LACERATION	2020-09-23 (30)/ 2020-09-23 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372290; Age (years): 19; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-28 (27)/ 2020-10-31 (30)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-10-28 (27)/ 2020-11-12 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372346; Age (years): 40; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal ulcer/ INTRANASAL ULCER- RIGHT	2020-10-06 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372346; Age (years): 40; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Actinic keratosis/ LEFT ARM ACTINIC KERATOSIS BELOW DELTOID MUSCLE.	2020-10-06 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant melanoma/ LEFT ABDOMEN MELANOMA	2020-10-06 (29)/ 2020-10-08 (31)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372384; Age (years): 81; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS BILATERAL ARMS	2020-09-24 (11)/ 2020-10-31 (48)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372427; Age (years): 61; Sex: F; Race: ASIAN							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Breast cancer/ MALIGNANT RIGHT BREAST TUMOR	2020-09-18 (3)/ 2020-10-20 (35)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3372433; Age (years): 43; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-30 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372446; Age (years): 51; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-02 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372449; Age (years): 58; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Food poisoning/ FOOD POISONING	2020-09-27 (5)/ 2020-09-27 (5)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3382004; Age (years): 32; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-17 (8)/ 2020-09-11 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ WORSENING OF URINARY TRACT INFECTION	2020-08-20 (11)/ 2020-08-21 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382007; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-11-17 (69)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382012; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-08-30 (20)/ 2020-09-08 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382016; Age (years): 38; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Back injury/ LOW BACK INJURY	2020-09-08 17:00 (1)/ 2020-09-15 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ EXACERBATION OF LOW BACK PAIN	2020-09-08 17:00 (1)/ 2020-09-15 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Immune system disorders/ Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2020-10-16 (39)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382042; Age (years): 40; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS OF THE FACE	2020-09-30 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Corneal abrasion/ CORNEAL ABRASION	2020-10-01 (18)/ 2020-10-04 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382060; Age (years): 65; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ PUNCTURE WOUND - LEFT THUMB	2020-09-26 (10)/ 2020-09-27 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382072; Age (years): 39; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ SPIDER BITE TO R LEG	2020-08-30 (12)/ 2020-09-08 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382085; Age (years): 41; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis allergic/ ALLERGIC RASH - UNKNOWN ETIOLOGY	2020-09-12 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382127; Age (years): 31; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-04 (9)/ 2020-09-12 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-04 (9)/ 2020-09-24 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-11 (16)/ 2020-09-11 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382152; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS FROM FIRE ANT BITES - BILATERAL LEGS	2020-09-07 (8)/ 2020-09-17 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Arthropod bite/ FIRE ARM BITES, BILATERAL LEGS	2020-09-07 (8)/ 2020-09-17 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural pain/ WISDOM TOOTH EXTRACTION PAIN	2020-10-19 (18)/ 2020-10-22 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-10-28 (27)/ 2020-11-11 (41)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3392040; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Cystitis/ ACUTE CYSTITIS	2020-11-13 (61)/ 2020-11-20 (68)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3392079; Age (years): 65; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Conjunctivitis/ CONJUNCTIVITIS RT EYE.	2020-09-20 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3392143; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-31 (32)/ 2020-11-02 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3392251; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-10-20 (13)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-20/)	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3392311; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-04 (23)/ 2020-11-06 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3392318; Age (years): 44; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foreign body/ FORIEGN BODY, RIGHT INDEX FINGER	2020-10-06 (19)/ 2020-10-06 (19)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-11 (27)/ 2020-11-11 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402001; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-19 (57)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402008; Age (years): 51; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-02 (40)/ 2020-10-12 (50)	Yes/ Yes/ No	2	No	NA/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402016; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-03 (40)/ 2020-10-14 (51)	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402018; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Corneal infection/ INFECTED RIGHT CORNIA	2020-09-19 (27)/ 2020-09-28 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402027; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Infected cyst/ INFECTED CYST ON NECK	2020-09-25 (33)/ 2020-11-07 (76)	Yes/ Yes/ No	2	No	NA/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402029; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-29 (37)/ 2020-10-12 (50)	Yes/ Yes/ No	4	Yes/3 (2020-10-07/ 2020-10-13)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402030; Age (years): 54; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-14 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402038; Age (years): 34; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Nasopharyngitis/ COMMON COLD	2020-09-15 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402061; Age (years): 73; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Granuloma/ GRANULOMA OF PHARYNX	2020-09-23 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402065; Age (years): 63; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Wound/ DRAINING OPEN WOUND	2020-10-09 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402074; Age (years): 27; Sex: F; Race: WHITE							
Nervous system disorders/ Carpal tunnel syndrome/ CARPAL TUNNEL SYNDROME/RIGHT WRIST	2020-08-12 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3402088; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Gardnerella infection/ GARDNERELLA	2020-09-02 (6)/ 2020-09-28 (32)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Colitis/ COLITIS	2020-09-26 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402094; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-30 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402096; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-20 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402185; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-23 (53)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402194; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-05 (65)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-16/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402211; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-07 (68)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402223; Age (years): 65; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Inguinal hernia/ INGUINAL HERNIA	2020-09-18 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402236; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media/ BILATERAL OTITISMEDIA	2020-10-14 (41)/ Ongoing	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Sinusitis/ RHINOSINUSITIS (SINUS INFECTION)	2020-10-14 (41)/ Ongoing	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402245; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-13 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402251; Age (years): 39; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ FRACTURED LEFT 4TH TOE	2020-09-16 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402258; Age (years): 64; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-31 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402261; Age (years): 34; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ FINGER STICK INJURY	2020-09-30 (28)/ 2020-09-30 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402269; Age (years): 45; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFFICIENCY	2020-08-20 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402299; Age (years): 50; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Post procedural haemorrhage/ POST OPERATIVE BLEEDING	2020-08-26 (19)/ 2020-09-01 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-26/ 2020-09-01)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3402308; Age (years): 64; Sex: M; Race: WHITE							
Eye disorders/ Cataract/ RIGHT EYE CATARACTS	2020-10-06 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Eye disorders/ Retinal haemorrhage/ DOT HEMORRHAGING RIGHT EYE	2020-10-06 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402308; Age (years): 64; Sex: M; Race: WHITE							
Eye disorders/ Vision blurred/ BLURRED VISION	2020-10-06 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	
Subject ID: US3402344; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-03 (17)/ 2020-10-15 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3402381; Age (years): 67; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-09-20 (7)/ Ongoing	Yes/ Yes/ No	2	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402382; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-26 (11)/ 2020-09-06 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3402382; Age (years): 66; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-08-28 (13)/ 2020-09-01 (17)	Yes/ Yes/ No	3	Yes/3 (2020-08-28/ 2020-09-01)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402383; Age (years): 44; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ ANT BITE	2020-09-08 (24)/ 2020-09-08 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402398; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABCESSED TOOTH	2020-11-13 (51)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3402405; Age (years): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Persistent depressive disorder/ WORSENING OF DYSTHYMIA	2020-10-12 (28)/ 2020-10-26 (42)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3402414; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LEFT HAND LACERATION	2020-10-21 (27)/ 2020-10-21 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3402415; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ POSITIVE COVID-19	2020-11-05 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402425; Age (years): 36; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2020-11-17 (54)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-17/)	NA/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402448; Age (years): 66; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Emphysema/ WORSENING OF EMPHYSEMA	2020-11-09 (20)/ 2020-11-11 (22)	Yes/ Yes/ No	3	Yes/3 (2020-11-09/ 2020-11-11)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT WAS SENT HOME ON 2 LITERS OF CONTINUOUS OXYGEN
Subject ID: US3412020; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-03 (39)/ 2020-10-20 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412022; Age (years): 50; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-07 (74)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412024; Age (years): 19; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis/ PERINASAL DERMATITIS - NOSE AND FACE.	2020-08-03 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3412047; Age (years): 70; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION	2020-08-22 (24)/ 2020-09-24 (57)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3412081; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-11-13 (75)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-13/)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3412086; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID-19	2020-08-23 (24)/ 2020-09-02 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412104; Age (years): 62; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin abrasion/ ABRASION OF RIGHT HAND	2020-08-17 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Chondromatosis/ SYNOVIAL OSTEOCHONDROMATOSIS LEFT KNEE	2020-08-17 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-08-17 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412107; Age (years): 39; Sex: F; Race: WHITE							
Psychiatric disorders/ Panic attack/ PANIC ATTACK	2020-08-16 (14)/ 2020-08-16 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412122; Age (years): 32; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABSCESSED TOOTH	2020-08-05 (2)/ 2020-09-08 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-06 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3412139; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREPTOCOCCAL PHARANGITIS	2020-08-12 (8)/ 2020-08-16 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412149; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ VIRAL SYNDROME - HUMAN RHINOVIRUS	2020-10-13 (41)/ 2020-10-25 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412158; Age (years): 73; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ CHRONIC OSTEOARTHRITIS (WORSENSING) - KNEES, SHOULDER AND WRIST	2020-08-28 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3412178; Age (years): 23; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING ANXIETY	2020-08-13 (4)/ 2020-08-20 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412185; Age (years): 43; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-09-02 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412185; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-09-08 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3412205; Age (years): 33; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection viral/ VIRAL RESPIRATORY INFECTION	2020-09-25 (17)/ 2020-10-24 (46)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Suspected COVID-19/ COVID LIKE ILLNESS	2020-11-03 (56)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3412224; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTED RIGHT INDEX FINGER	2020-08-17 (4)/ 2020-10-08 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412227; Age (years): 66; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Meniscus injury/ L MENISCAL TEAR (LEFT KNEE)	2020-08-25 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3412234; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Gingivitis/ GINGIVITIS	2020-08-23 (11)/ 2020-09-07 (26)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412259; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-03 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3412270; Age (years): 77; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-28 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412284; Age (years): 54; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dyspepsia/ HEART BURN	2020-09-24 (8)/ 2020-09-25 (9)	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3412291; Age (years): 59; Sex: M; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS/ENTEROVIRUS	2020-10-20 (28)/ 2020-11-06 (45)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412300; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-11-02 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3412304; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-03 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412306; Age (years): 49; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Blister/ VESICLES - RIGHT INDEX FINGER	2020-10-08 (18)/ 2020-10-19 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3412318; Age (years): 59; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	2020-09-11 (18)/ 2020-09-30 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412328; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN (ETIOLOGY - UNDETERMINED)	2020-09-05 (11)/ 2020-10-01 (37)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412328; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ ATYPICAL CHEST PAIN	2020-09-17 (23)/ 2020-09-18 (24)	Yes/ Yes/ No	4	Yes/3 (2020-09-17/ 2020-09-18)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3412357; Age (years): 32; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRETORY INFECTION	2020-09-26 (25)/ 2020-09-28 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422006; Age (years): 39; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-26 (15)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3422009; Age (years): 74; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ DENTAL ABSCESS	2020-08-28 (16)/ 2020-09-07 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422011; Age (years): 39; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Femoral hernia/ FEMORAL HERNIA	2020-08-20 (8)/ 2020-08-28 (16)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422021; Age (years): 31; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARICONOMA ON NOSE	2020-09-22 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3422038; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS	2020-11-23 (70)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422063; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-31 (12)/ 2020-09-14 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422068; Age (years): 72; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA	2020-09-03 (15)/ 2020-09-25 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422082; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Hand fracture/ RIGHT BROKEN RING FINGER	2020-09-19 11:30 (1)/ 2020-10-21 08:00 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422087; Age (years): 57; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS/POISON IVY	2020-10-08 (18)/ 2020-10-12 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422107; Age (years): 44; Sex: F; Race: WHITE							
Nervous system disorders/ Thoracic radiculopathy/ PINCHED NERVE UPPER BACK	2020-11-12 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3422118; Age (years): 47; Sex: F; Race: ASIAN							
Blood and lymphatic system disorders/ Iron deficiency anaemia/ IRON DEFICIENCY ANEMIA	2020-09-25 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3422149; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-10-25 (28)/ 2020-11-19 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422152; Age (years): 61; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ TYPE 2 DIABETES	2020-09-21 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422177; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-04 (6)/ 2020-10-15 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422220; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Bursitis/ BURSITIS, HIP	2020-09-16 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-10-29 (18)/ 2020-11-11 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422230; Age (years): 81; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA DIAGNOSIS	2020-09-18 (11)/ 2020-09-18 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ SYNVISC KNEE INJECTION FOR OSTEOARTHRITIS	2020-09-28 (21)/ 2020-09-28 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422248; Age (years): 66; Sex: M; Race: WHITE							
Vascular disorders/ Aortic aneurysm/ AORTIC ANEURYSM	2020-09-25 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422248; Age (years): 66; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ LEFT HEEL FRACTURE	2020-11-23 (48)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3422264; Age (years): 61; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Renal and urinary disorders/ Haematuria/ HEMATURIA	2020-10-09 08:00 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3422269; Age (years): 40; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ FOOT LACERATION, LEFT	2020-09-14 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3422281; Age (years): 65; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS	2020-10-27 (14)/ 2020-10-28 (15)	Yes/ Yes/ No	3	Yes/3 (2020-10-27/ 2020-10-28)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422286; Age (years): 59; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-07 (22)/ 2020-10-14 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422288; Age (years): 61; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ FINGER LACERATION	2020-11-01 (19)/ 2020-11-01 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422310; Age (years): 62; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIAS	2020-10-17 (20)/ 2020-10-20 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422311; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-02 (8)/ 2020-11-19 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422311; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Pharyngitis streptococcal/ STREPTOCOCCAL PHARYNGITIS	2020-11-13 (19)/ 2020-11-23 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432017; Age (years): 54; Sex: F; Race: WHITE							
Eye disorders/ Vitreous floaters/ FLOATER (LEFT EYE)	2020-08-31 (27)/ 2020-10-27 (84)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432023; Age (years): 83; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Polymyalgia rheumatica/ POSSIBLE POLYMYALGIA RHEUMATICA	2020-08-20 (16)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-21)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432031; Age (years): 39; Sex: F; Race: WHITE							
Psychiatric disorders/ Seasonal affective disorder/ ANXIETY/ SEASONAL DEPRESSION	2020-10-07 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432041; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Synovial cyst/ LEFT KNEE BAKER'S CYST	2020-09-03 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Oral candidiasis/ ORAL CANDIDIASIS	2020-11-12 (71)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432067; Age (years): 69; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ LEFT THIGH IN SITU SQUAMOUS CELL CARCINOMA	2020-09-30 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3432068; Age (years): 60; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-20 (13)/ 2020-09-24 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-21 (14)/ 2020-09-21 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432074; Age (years): 55; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN (EXACERBATION)	2020-08-26 (17)/ 2020-09-30 (52)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-09-03 (25)/ 2020-09-18 (40)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432090; Age (years): 66; Sex: F; Race: WHITE							
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-10-02 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-26 (48)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432113; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-08-30 (19)/ 2020-09-04 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432120; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-28 (21)/ 2020-09-30 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432126; Age (years): 25; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-05 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432135; Age (years): 32; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-30 (21)/ 2020-10-08 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432139; Age (years): 22; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ VASOVAGAL/SYNCOPAL EPISODE	2020-09-15 (1)/ 2020-09-15 (1)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432144; Age (years): 52; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Glucose tolerance impaired/ PRE-DIABETES	2020-09-18 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	2020-10-09 (29)/ 2020-10-09 (29)	Yes/ Yes/ No	2	No	NR/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432146; Age (years): 67; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ LEFT ROTATOR CUFF SPRAIN	2020-10-27 (47)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432150; Age (years): 71; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-11-08 (59)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3432161; Age (years): 20; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-10-30 (49)/ 2020-11-04 (54)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432173; Age (years): 26; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-10-02 (19)/ 2020-10-08 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432183; Age (years): 26; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT (SORE THROAT)	2020-09-30 (3)/ 2020-10-03 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432183; Age (years): 26; Sex: F; Race: WHITE							
Nervous system disorders/ Seizure/ SEIZURE	2020-10-09 (12)/ 2020-10-09 (12)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432202; Age (years): 77; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foreign body/ FOREIGN BODY IN FOOT	2020-08-20 (2)/ 2020-09-02 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertensive urgency/ HYPERTENSIVE URGENCY	2020-09-25 (10)/ 2020-09-30 (15)	Yes/ Yes/ No	3	Yes/3 (2020-09-25/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-02 (17)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432208; Age (years): 54; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ SPINAL STENOSIS	2020-09-07 (19)/ 2020-10-05 (47)	Yes/ Yes/ No	3	Yes/3 (2020-10-02/ 2020-10-05)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432244; Age (years): 27; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-30 (42)/ 2020-11-01 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432249; Age (years): 65; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ SHOULDER PAIN (LEFT)	2020-09-01 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432260; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-02 (10)/ 2020-09-12 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Surgical and medical procedures/ Spinal fusion surgery/ CERVICAL FUSION C5-C6	2020-11-04 (45)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-04/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3432265; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-10-27 (37)/ 2020-11-04 (45)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432266; Age (years): 58; Sex: M; Race: WHITE							
Infections and infestations/ Hordeolum/ STYE ON THE RIGHT EYE	2020-09-02 (10)/ 2020-10-20 (58)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432275; Age (years): 69; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Tympanic membrane perforation/ TYMPANIC MEMBRANE PERFORATION	2020-10-06 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432287; Age (years): 77; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Ear congestion/ EAR FULLNESS (RIGHT)	2020-09-29 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3432289; Age (years): 27; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-11-05 (45)/ 2020-11-23 (63)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432291; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ Respiratory tract infection viral/ RESPIRATORY VIRAL SYNDROME	2020-09-06 (12)/ 2020-09-08 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432295; Age (years): 83; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis bullous/ DIFFUSE BULLOUS RASH (NON-URTICARIAL)	2020-09-12 (18)/ 2020-10-02 (38)	Yes/ Yes/ No	4	Yes/1/3 (2020-09-17/ 2020-09-24)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	FATAL
Blood and lymphatic system disorders/ Lymphadenopathy/ SUPRACLAVICULAR LYMPHADENOPATHY	2020-09-22 (28)/ 2020-10-02 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432295; Age (years): 83; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Systemic inflammatory response syndrome/ SEVERE SYSTEMIC INFLAMMATORY SYNDROME IN THE SETTING OF CLL	2020-10-01 (37)/ 2020-10-02 (38)	Yes/ Yes/ No	4	Yes/1/3 (2020-10-01/ 2020-10-02)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	FATAL
Subject ID: US3432329; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ CRACKED TOOTH	2020-10-06 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432335; Age (years): 31; Sex: F; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-29 (5)/ 2020-10-06 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432344; Age (years): 77; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-13 (19)/ 2020-11-02 (39)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432352; Age (years): 61; Sex: M; Race: WHITE							
Eye disorders/ Eye ulcer/ EYE ULCER	2020-10-27 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3432357; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-09-11 (14)/ 2020-09-12 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432362; Age (years): 72; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM PAIN	2020-10-06 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432386; Age (years): 34; Sex: F; Race: MULTIPLE:				(b) (6)			
Infections and infestations/ Latent tuberculosis/ LATENT TUBERCULOSIS	2020-09-25 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432387; Age (years): 33; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-16 (47)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432410; Age (years): 61; Sex: M; Race: WHITE							
Infections and infestations/ Pulpitis dental/ R LOWER MOLAR INFLAMMATION S/P CROWN REPAIR	2020-10-30 (30)/ 2020-11-13 (44)	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432426; Age (years): 33; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP PHARYNGITIS	2020-09-28 (25)/ 2020-10-08 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432444; Age (years): 31; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-17 (13)/ 2020-10-21 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432452; Age (years): 66; Sex: M; Race: OTHER: (b) (6)							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-03 09:50 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432463; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-23 (18)/ 2020-11-01 (27)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432467; Age (years): 42; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ CAVITY	2020-09-14 (7)/ 2020-09-15 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432475; Age (years): 73; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ LEFT EAR TUBE INFECTION	2020-10-02 (24)/ 2020-10-02 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432489; Age (years): 25; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Upper respiratory tract infection/ URI	2020-10-28 (21)/ 2020-11-03 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432502; Age (years): 78; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-11-11 (30)/ 2020-11-15 (34)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432529; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-29 (8)/ 2020-09-30 (9)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432539; Age (years): 43; Sex: M; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-10-28 (12)/ 2020-11-09 (24)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432566; Age (years): 27; Sex: F; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Tendonitis/ TENDONITIS R FOOT	2020-10-07 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432585; Age (years): 30; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Costochondritis/ COSTOCHONDRITIS	2020-10-25 (24)/ 2020-11-03 (33)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432596; Age (years): 41; Sex: F; Race: MULTIPLE: (b) (6)							
Ear and labyrinth disorders/ Tympanic membrane perforation/ PERFORATED EARDRUM	2020-10-25 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432599; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ WORSENING LEFT SHOULDER NERVE IMPINGEMENT	2020-10-24 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432610; Age (years): 32; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-10-20 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-10-20 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432636; Age (years): 27; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (URI)	2020-10-26 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3442052; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-09-08 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3442065; Age (years): 35; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-13 (57)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Investigations/ Breath sounds abnormal/ DECREASED BREATH SOUNDS BILATERALLY	2020-11-18 (62)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442067; Age (years): 86; Sex: F; Race: WHITE							
Surgical and medical procedures/ Tooth extraction/ TOOTH PULLED	2020-09-03 (14)/ 2020-09-03 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Eye disorders/ Conjunctival irritation/ BILATERAL IRRITATION OF CONJUNCTIVA	2020-10-05 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3442069; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ POSITIVE COVID-19	2020-11-05 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-11-06 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442099; Age (years): 73; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pharyngeal erythema/ RED PHARYNX	2020-11-10 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Upper-airway cough syndrome/ POST NASAL DRIP (CLEAR)	2020-11-10 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN
Subject ID: US3442121; Age (years): 35; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH ON NECK	2020-10-22 (21)/ 2020-10-25 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Helicobacter infection/ H PYLORI	2020-10-22 (21)/ 2020-10-26 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442132; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	2020-11-19 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3442163; Age (years): 78; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-19 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pharyngeal erythema/ ERYTHEMA: PHARYNX	2020-10-21 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3452035; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-03 (72)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452047; Age (years): 26; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREPTOCOCCUS PHARYNGITIS	2020-10-20 (57)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3452057; Age (years): 26; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-01 (5)/ 2020-09-04 (8)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452099; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-08-18 (18)/ 2020-08-20 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-08-18 (18)/ 2020-08-21 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452099; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-18 (18)/ 2020-08-26 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452130; Age (years): 30; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-14 (76)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3452189; Age (years): 51; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID -19 INFECTION	2020-09-24 (23)/ 2020-10-04 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3452203; Age (years): 80; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-17 (76)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452206; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-20 (79)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3452295; Age (years): 62; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-08-06 16:40 (1)/ 2020-08-25 (20)	No/ Yes/ No	1	No	NA/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452369; Age (years): 42; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-15 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3462111; Age (years): 57; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Laryngeal oedema/ LARYNGEAL EDEMA	2020-09-19 (5)/ 2020-09-24 (10)	Yes/ Yes/ No	4	Yes/3 (2020-09-19/ 2020-09-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462112; Age (years): 68; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ RIGHT KIDNEY STONE	2020-08-31 (21)/ 2020-09-24 (45)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462116; Age (years): 43; Sex: F; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE	2020-09-03 08:00 (23)/ 2020-09-09 17:00 (30)	Yes/ Yes/ No	4	Yes/3 (2020-09-05/ 2020-09-09)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Cardiac disorders/ Cardiomyopathy/ FAMILIAL CARDIOMYOPATHY	2020-09-05 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462161; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS FLARE	2020-09-02 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3462180; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-04 18:00 (55)/ 2020-11-11 (62)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462181; Age (years): 62; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-31 (52)/ 2020-11-04 (56)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462187; Age (years): 51; Sex: F; Race: NOT REPORTED							
Injury, poisoning and procedural complications/ Contusion/ BACK CONTUSION	2020-09-05 (23)/ 2020-09-07 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462203; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-08-26 (10)/ 2020-08-30 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3462255; Age (years): 57; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2020-10-16 08:00 (30)/ 2020-10-17 12:00 (31)	Yes/ Yes/ No	4	Yes/3 (2020-10-16/ 2020-10-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-16 08:00 (30)/ 2020-10-17 12:00 (31)	Yes/ Yes/ No	4	Yes/3 (2020-10-16/ 2020-10-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462288; Age (years): 55; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-26 (6)/ 2020-09-01 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462299; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (48)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3462357; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES OUTBREAK	2020-10-12 (19)/ 2020-10-22 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462385; Age (years): 41; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Asthma/ INCREASE IN ASTHMA SYMPTOMS	2020-09-19 (23)/ 2020-10-01 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462388; Age (years): 46; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pneumonia aspiration/ ASPIRATION PNEUMONIA	2020-09-25 (26)/ 2020-10-04 (35)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3462402; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media/ LEFT EAR OTITIS MEDIA	2020-10-08 (10)/ 2020-10-16 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3472025; Age (years): 72; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ TENDONITIS	2020-09-11 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472047; Age (years): 54; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-16 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3472051; Age (years): 39; Sex: M; Race: ASIAN							
Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE ELEVATED	2020-10-01 (16)/ 2020-10-09 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472057; Age (years): 52; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS	2020-09-19 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Cellulitis/ CELLULITIS	2020-10-12 15:00 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472061; Age (years): 45; Sex: F; Race: ASIAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-29 (9)/ 2020-10-05 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3472064; Age (years): 51; Sex: F; Race: NOT REPORTED							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-30 (10)/ 2020-10-05 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3472096; Age (years): 42; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3472130; Age (years): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-11-03 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482001; Age (years): 71; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-05 (27)/ 2020-09-14 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOLS	2020-09-06 (28)/ 2020-09-13 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482003; Age (years): 82; Sex: M; Race: WHITE							
Infections and infestations/ Localised infection/ LEFT LITTLE TOE INFECTION	2020-09-12 (5)/ 2020-09-25 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482029; Age (years): 71; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ ACUTE FLARE OF CHRONIC LOW BACK PAIN	2020-09-30 (22)/ 2020-10-16 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482045; Age (years): 58; Sex: M; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-10-12 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482047; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Denture stomatitis/ ORAL ULCER, SECONDARY TO MISFITTING DENTURES	2020-10-05 (26)/ 2020-10-31 (52)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-12 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482047; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Nasopharyngitis/ COMMON COLD	2020-10-30 (51)/ 2020-11-12 (64)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482052; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Staphylococcal skin infection/ PARTICIPANT DEVELOPED A STAPH INFECTION ON HIS THIGH. PARTICIPANT WAS EVALUATED AND TREATED BY HIS PCP. STARTED ON RX FOR DOXYCYCLINE X 5 DAYS.	2020-08-19 (6)/ 2020-08-31 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482052; Age (years): 52; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Injection related reaction/ SOLICITED LOCAL OR SYSTEMIC AR LASTING BEYOND 7 DAYS POST INJECTION. REPORTED HEADACHES, FATIGUE, MUSCLE ACHES, AND JOINT ACHES.	2020-09-08 (1)/ 2020-09-18 (11)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3482060; Age (years): 71; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site bruising/ LEFT ARM INJECTION SITE BRUISING FOLLOWING RECEIPT OF INFLUENZA VACCINE	2020-09-26 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482063; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT ANTERIOR CERVICAL LYMPHADENOPATHY IPSILATERAL TO VACCINATION SITE	2020-09-15 18:00 (2)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482085; Age (years): 73; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rosacea/ ROSACEA WORSENING	2020-09-20 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482086; Age (years): 74; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ NON CARDIAC PLEURITIC CHEST TIGHTNESS	2020-09-16 (1)/ 2020-09-29 (14)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482086; Age (years): 74; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ NON-PRODUCTIVE COUGH	2020-09-17 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ RESPIRATORY TRACT CHEST CONGESTION	2020-09-17 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Bronchitis/ ACUTE BRONCHITIS	2020-10-19 (34)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482094; Age (years): 48; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-10 (19)/ 2020-10-16 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-10 (19)/ 2020-10-18 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-10 (19)/ 2020-10-19 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482094; Age (years): 48; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES, GENERALIZED	2020-10-10 (19)/ 2020-10-19 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIAS, GENERALIZED	2020-10-10 (19)/ 2020-10-19 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482098; Age (years): 70; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-28 (12)/ 2020-10-03 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-28 (12)/ 2020-10-03 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482098; Age (years): 70; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE LEFT SIDE	2020-10-01 (15)/ 2020-10-03 (17)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482111; Age (years): 57; Sex: M; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Nervous system disorders/ Hypoaesthesia/ RIGHT SIDED THUMB AND INDEX FINGER NUMBNESS	2020-08-31 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482116; Age (years): 39; Sex: F; Race: MULTIPLE:					(b) (6)		
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-07 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-15 (18)/ 2020-10-23 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3482121; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-11 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3482145; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Cardiac failure acute/ ACUTE CARDIAC HEART FAILURE EXACERBATION	2020-09-02 (8)/ 2020-09-13 (19)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-02/ 2020-09-13)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Streptococcal sepsis/ SEPSIS RELATED TO STREPTOCOCCUS BACTEREMIA	2020-09-02 (8)/ 2020-09-13 (19)	Yes/ Yes/ No	4	Yes/3 (2020-09-02/ 2020-09-13)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Gout/ GOUT EXACERBATION IN RIGHT KNEE	2020-09-26 (32)/ 2020-09-30 (36)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482145; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Renal and urinary disorders/ Chronic kidney disease/ ACUTE EXACERBATION OF CHRONIC KIDNEY DISEASE STAGE III	2020-09-26 (32)/ 2020-09-30 (36)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-09-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Anaemia/ EXACERBATION OF ANEMIA	2020-10-22 (58)/ 2020-10-26 (62)	Yes/ Yes/ No	3	Yes/3 (2020-10-22/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Cardiac disorders/ Cardiac failure acute/ ACUTE DECOMPENSATED HEART FAILURE	2020-11-09 (76)/ 2020-11-10 (77)	Yes/ Yes/ No	4	Yes/3 (2020-11-09/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482150; Age (years): 78; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Inguinal hernia/ RECURRENT INGUINAL HERNIA OF RIGHT SIDE	2020-10-01 (8)/ 2020-11-03 (41)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3482160; Age (years): 76; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin abrasion/ ABRASION [FROM FALL]	2020-08-31 (4)/ 2020-09-21 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482171; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ Rhinitis/ WORSENING CHRONIC RHINITIS	2020-09-14 (15)/ 2020-09-30 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482181; Age (years): 43; Sex: M; Race: NOT REPORTED							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-02 11:00 (2)/ 2020-09-02 13:30 (2)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482188; Age (years): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-01 (31)/ 2020-10-16 (46)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-01 (31)/ 2020-10-16 (46)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-01 (31)/ 2020-10-16 (46)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482200; Age (years): 72; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Aphthous ulcer/ APTHOUS ULCERS-MULTIPLE	2020-09-21 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482205; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-11-06 (38)/ 2020-11-13 (45)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482208; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Insomnia/ INSOMNIA	2020-09-06 (5)/ 2020-09-30 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Lower respiratory tract congestion/ CHEST CONGESTION (RESPIRATORY)	2020-09-21 (20)/ 2020-09-25 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482208; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Abdominal discomfort/ GI DISTRESS	2020-09-24 (23)/ 2020-09-29 (28)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	2020-09-25 (24)/ 2020-09-25 (24)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Folliculitis/ LEFT ARMPIT HAIR FOLLICLE INFLAMMATION	2020-10-11 (12)/ 2020-11-05 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482214; Age (years): 53; Sex: M; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ UPPER RESPIRATORY INFECTION (RHINOVIRUS)	2020-09-12 (10)/ 2020-09-16 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482228; Age (years): 42; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Tooth impacted/ IMPACTED WISDOM TOOTH	2020-10-18 (17)/ 2020-11-12 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482233; Age (years): 69; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin lesion/ SKIN LESION RIGHT SHIN		Yes/ Yes/ No		No			
Subject ID: US3482235; Age (years): 54; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-09-28 (25)/ 2020-10-13 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482251; Age (years): 82; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin mass/ CUTANEOUS NODULE RIGHT UPPER ARM	2020-09-09 22:18 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482251; Age (years): 82; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Oedema peripheral/ LEFT LOWER LEG EDEMA	2020-09-12 (5)/ 2020-10-14 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482257; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Immune system disorders/ Seasonal allergy/ EXACERBATION OF SEASONAL ALLERGIES	2020-10-06 (28)/ 2020-10-15 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482267; Age (years): 78; Sex: F; Race: WHITE							
Nervous system disorders/ Presyncope/ VASOVAGAL SYNDROME	2020-10-08 12:56 (1)/ 2020-10-08 14:30 (1)	Yes/ Yes/ No	3	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482277; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	2020-09-15 (5)/ 2020-09-27 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482277; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-08 18:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482297; Age (years): 41; Sex: F; Race: MULTIPLE: (b) (6)							
Surgical and medical procedures/ Tooth repair/ LEFT SIDED MOLAR REPAIR	2020-10-21 (7)/ 2020-10-21 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482324; Age (years): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Abdominal pain lower/ RIGHT LOWER ABDOMINAL PAIN	2020-10-30 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Reproductive system and breast disorders/ Ovarian cyst ruptured/ RUPTURED RIGHT OVARIAN CYST	2020-10-30 (8)/ 2020-11-02 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492014; Age (years): 64; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS LEFT THIGH	2020-11-04 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3492020; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-11 (17)/ 2020-10-16 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-11 (17)/ 2020-10-16 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-12 (18)/ 2020-10-14 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492020; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Peripheral swelling/ RIGHT ARM SWELLING	2020-10-12 (18)/ 2020-10-16 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT ARM PAIN	2020-10-12 (18)/ 2020-10-16 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Scab/ RIGHT ARM SCAB	2020-10-12 (18)/ 2020-10-30 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492027; Age (years): 78; Sex: F; Race: WHITE							
Infections and infestations/ Otitis externa/ OTITIS EXTERNA	2020-09-24 (27)/ 2020-10-01 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492031; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-09-25 13:00 (1)/ 2020-09-25 13:05 (1)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492043; Age (years): 58; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-28 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3492054; Age (years): 40; Sex: M; Race: ASIAN							
Reproductive system and breast disorders/ Prostatitis/ NONBACTERIAL PROSTATITIS	2020-09-25 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3492060; Age (years): 39; Sex: M; Race: NOT REPORTED							
Gastrointestinal disorders/ Dental caries/ CAVITY	2020-10-06 (5)/ 2020-10-20 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492064; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Asymptomatic COVID-19/ ASYMPTOMATIC COVID-19 INFECTION	2020-10-31 (30)/ 2020-11-11 (41)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Cerebrovascular accident/ CEREBROVASCULAR ACCIDENT	2020-10-31 (30)/ 2020-11-11 (41)	Yes/ Yes/ No	3	Yes/3 (2020-10-31/ 2020-11-11)/4	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: RIGHT LOWER EXTREMITY WEAKNESS
Subject ID: US3492071; Age (years): 49; Sex: M; Race: ASIAN							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-11 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3492085; Age (years): 29; Sex: F; Race: NOT REPORTED							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-09-24 (17)/ 2020-10-09 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492085; Age (years): 29; Sex: F; Race: NOT REPORTED							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-09-24 (17)/ 2020-10-25 (48)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492090; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-15 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-15 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492090; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-10-15 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-15 (10)/ 2020-10-25 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492096; Age (years): 68; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-05 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3492099; Age (years): 65; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	2020-09-20 (12)/ 2020-09-27 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3492117; Age (years): 61; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ COVID-19/ COVID 19, CONFIRMED	2020-09-22 (13)/ 2020-10-05 (26)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492127; Age (years): 30; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ RIGHT EAR INFECTION	2020-10-26 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3492138; Age (years): 47; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Investigations/ Vitamin B12 decreased/ LOW VITAMIN B12 LEVEL	2020-09-17 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Investigations/ Vitamin D decreased/ LOW VITAMIN D LEVEL	2020-09-17 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492152; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ PULLED GROIN MUSCLE	2020-09-26 (13)/ 2020-10-05 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492162; Age (years): 68; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS L KNEE	2020-10-29 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3492219; Age (years): 23; Sex: F; Race: WHITE							
Infections and infestations/ Paronychia/ PARONYCHIA	2020-09-21 12:00 (1)/ 2020-09-24 12:00 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-11-11 (24)/ 2020-11-11 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3492242; Age (years): 29; Sex: M; Race: MULTIPLE:						(b) (6)	
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-09-29 (7)/ 2020-10-22 (30)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492247; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-25 (3)/ 2020-10-09 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492258; Age (years): 27; Sex: F; Race: ASIAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-01 (7)/ 2020-10-06 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492280; Age (years): 46; Sex: F; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Myxoid cyst/ DIGITAL MIXOID CYST (RIGHT INDEX FINGER)	/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492290; Age (years): 21; Sex: F; Race: ASIAN							
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-10-15 (11)/ 2020-10-18 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492298; Age (years): 39; Sex: F; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ DRY COUGH	2020-10-20 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3502045; Age (years): 55; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ MIGRAINE EXACERBATION	2020-09-16 (20)/ 2020-09-23 (27)	Yes/ Yes/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502057; Age (years): 52; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-16 (20)/ 2020-09-17 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502057; Age (years): 52; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (20)/ 2020-09-17 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-09-16 (20)/ 2020-09-17 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-16 (20)/ 2020-09-17 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502083; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Otitis externa/ ACUTE OTITIS EXTERNA	2020-09-10 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502083; Age (years): 66; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-17 (18)/ 2020-10-25 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502088; Age (years): 44; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Glucose tolerance impaired/ PREDIABETES	2020-10-21 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3502097; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-05 09:00 (1)/ 2020-09-13 12:00 (10)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502097; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-09-05 09:00 (1)/ 2020-09-13 12:00 (10)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-05 09:00 (1)/ 2020-09-17 12:00 (14)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-05 09:00 (1)/ 2020-09-17 12:00 (14)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-05 09:00 (1)/ 2020-09-17 12:00 (14)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502097; Age (years): 61; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA - INTERMITTENT	2020-09-05 09:00 (1)/ 2020-09-22 12:00 (19)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-05 09:00 (1)/ 2020-09-22 12:00 (19)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-13 (10)/ 2020-09-20 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Stomatitis/ STOMATITIS	2020-11-05 (35)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502123; Age (years): 54; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ FINGER LACERATION	2020-09-29 (21)/ 2020-09-29 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502134; Age (years): 51; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-10 (3)/ 2020-10-20 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502142; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Multiple sclerosis/ MULTIPLE SCLEROSIS	2020-11-12 (38)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-12/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3502149; Age (years): 64; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-10-14 (8)/ 2020-10-21 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502149; Age (years): 64; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Ear congestion/ CONGESTION- EARS	2020-10-14 (8)/ 2020-10-23 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-19 (13)/ 2020-10-20 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-19 (13)/ 2020-10-22 (16)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-19 (13)/ 2020-10-22 (16)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502149; Age (years): 64; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-19 (13)/ 2020-10-23 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502165; Age (years): 35; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-11-05 (23)/ 2020-11-10 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-05 (23)/ 2020-11-14 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502177; Age (years): 50; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Gout/ GOUT EXACERBATION	2020-10-03 (9)/ 2020-10-08 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502177; Age (years): 50; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2020-10-03 (9)/ 2020-10-10 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502188; Age (years): 36; Sex: M; Race: WHITE							
Renal and urinary disorders/ Haematuria/ HEMATURIA	2020-10-16 (12)/ 2020-10-16 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502198; Age (years): 65; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ NONPRODUCTIVE COUGH	2020-10-29 (21)/ 2020-11-04 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502214; Age (years): 73; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-05 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502214; Age (years): 73; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-11-09 (19)/ 2020-11-12 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502216; Age (years): 39; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Immune system disorders/ Anaphylactic reaction/ ANAPHYLAXIS	2020-11-02 (11)/ 2020-11-02 (11)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-11-02 (11)/ 2020-11-02 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3512003; Age (years): 59; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN, CROWN OF SCALP	2020-09-26 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512009; Age (years): 78; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Lip swelling/ ALLERGIC REACTION OF INTERMITTENT LIP SWELLING	2020-09-17 (2)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512010; Age (years): 74; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-21 (18)/ 2020-09-28 (25)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-21 (18)/ 2020-10-01 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3512010; Age (years): 74; Sex: F; Race: WHITE							
Infections and infestations/ Hordeolum/ STYE RIGHT EYE	2020-11-06 (64)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512033; Age (years): 33; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-24 (14)/ 2020-09-28 (18)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512038; Age (years): 69; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING LEFT MEDIAL KNEE PAIN	2020-08-24 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3512064; Age (years): 65; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ LEFT POSTERIOR TENDONITIS	2020-10-06 (27)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512081; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Cyst/ RIGHT MEDIAL KNEE BENIGN CYST	2020-09-28 (18)/ 2020-10-05 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3512082; Age (years): 68; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ EXERCISE WORSENED BACK MUSCLE SPASMS	2020-10-19 (39)/ 2020-10-29 (49)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3512082; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Hordeolum/ RIGHT HORDEOLUM	2020-10-30 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Hordeolum/ LEFT HORDEOLUM	2020-11-04 (55)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512092; Age (years): 64; Sex: M; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS FLARE	2020-10-23 (43)/ 2020-10-26 (46)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512114; Age (years): 77; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-11-14 (59)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512116; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512160; Age (years): 46; Sex: M; Race: WHITE							
Nervous system disorders/ Sciatica/ LEFT SCIATICA	2020-09-08 (14)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512172; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-24 20:00 (1)/ 2020-10-02 06:00 (8)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-24 20:00 (1)/ 2020-11-05 06:00 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512179; Age (years): 32; Sex: M; Race: WHITE							
Infections and infestations/ Oral herpes/ COLD SORE IN MOUTH ON RIGHT LOWER GUM	2020-09-28 (31)/ 2020-10-20 (53)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512181; Age (years): 78; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA OF RIGHT CHEEK	2020-09-01 (4)/ 2020-10-01 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3512186; Age (years): 36; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA ON BACK	2020-09-03 09:00 (2)/ 2020-09-03 10:00 (2)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512206; Age (years): 75; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA ON SCALP	2020-09-16 (14)/ 2020-09-29 (27)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3512232; Age (years): 45; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-05 (5)/ 2020-10-09 (9)	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512248; Age (years): 76; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-17 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512248; Age (years): 76; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT LATERAL HIP PAIN	2020-10-05 (26)/ 2020-10-05 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512265; Age (years): 58; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ MODERATE BENIGN PROSTATIC HYPERPLASIA	2020-09-17 16:25 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522042; Age (years): 34; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-22 (16)/ 2020-08-30 (24)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522045; Age (years): 32; Sex: M; Race: ASIAN							
Ear and labyrinth disorders/ Tympanic membrane perforation/ SPONTANEOUS RUPTURE OF TYMPANIC MEMBRANE	2020-10-26 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Otitis media acute/ NON-RECURRENT ACUTE SUPPURATIVE OTITIS MEDIA OF RIGHT EAR	2020-10-26 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522048; Age (years): 54; Sex: F; Race: MULTIPLE: (b) (6)							
Metabolism and nutrition disorders/ Glucose tolerance impaired/ DIAGNOSED WITH PRE DIABETES	2020-08-07 07:00 (1)/ Ongoing	No/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522060; Age (years): 37; Sex: F; Race: ASIAN							
Infections and infestations/ Tooth infection/ LEFT LOWER WISDOM TOOTH INFECTION	2020-10-27 (49)/ 2020-11-03 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522071; Age (years): 72; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Ear discomfort/ PRESSURE IN RIGHT EAR	2020-10-20 (47)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-26 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522077; Age (years): 62; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISMS (RIGHT MAIN PULMONARY ARTERY, LEFTS LOWER LOBAR BRANCH)	2020-10-15 (36)/ 2020-10-19 (40)	Yes/ Yes/ No	4	Yes/3 (2020-10-17/ 2020-10-19)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522099; Age (years): 69; Sex: F; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA EXACERBATION	2020-09-11 (3)/ 2020-10-04 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522105; Age (years): 37; Sex: M; Race: ASIAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-24 (47)/ 2020-10-31 (54)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522128; Age (years): 70; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Atrial fibrillation/ EPISODE OF AFIB	2020-08-27 (14)/ 2020-08-27 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Atrial flutter/ ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE	2020-09-25 (15)/ 2020-09-27 (17)	Yes/ Yes/ No	4	Yes/3 (2020-09-25/ 2020-09-27)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Pneumonia/ MULTIFOCAL PNEUMONIA IN BOTH LUNGS	2020-10-08 (28)/ 2020-10-12 (32)	Yes/ Yes/ No	4	Yes/3 (2020-10-08/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Gout/ GOUT FLAIR	2020-10-10 (30)/ 2020-10-11 (31)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522163; Age (years): 54; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS OF THE ENTIRE BODY	2020-08-19 (3)/ 2020-08-20 (4)	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522166; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-08-28 (11)/ 2020-09-08 (22)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Lumbar radiculopathy/ LUMBAR RADICULOPATHY	2020-08-29 (12)/ 2020-09-08 (22)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Back injury/ BACK MUSCLE INJURY	2020-11-07 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522166; Age (years): 36; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-11-07 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3522218; Age (years): 59; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19 INFECTION	2020-11-14 (60)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522233; Age (years): 21; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria papular/ URTICARIAL, PAPULAR RASH, UNKNOWN ETIOLOGY	2020-10-07 (16)/ 2020-10-25 (34)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522257; Age (years): 58; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Menopausal symptoms/ HOT FLASHES (MENOPAUSE)	2020-10-22 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522269; Age (years): 44; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-07 (18)/ 2020-09-15 (26)	Yes/ Yes/ No	4	Yes/3 (2020-09-12/ 2020-09-16)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-08 (19)/ 2020-09-15 (26)	Yes/ Yes/ No	4	Yes/3 (2020-09-12/ 2020-09-16)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-08 (19)/ 2020-09-15 (26)	Yes/ Yes/ No	4	Yes/3 (2020-09-12/ 2020-09-16)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522294; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ HIP PAIN	2020-10-12 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522307; Age (years): 31; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-09-21 17:00 (1)/ 2020-10-11 17:00 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522333; Age (years): 54; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Paraesthesia/ PARESTHESIA (FACE, HANDS, ARMS, LEGS, FEET)	2020-10-06 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522442; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Herpes zoster/ POSSIBLE SHINGLES	2020-10-05 (6)/ 2020-10-21 (22)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522461; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Rhinitis/ RHINITIS	2020-10-05 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3522461; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ COPD EXACERBATION	2020-10-10 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522509; Age (years): 44; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS OF TRUNK AREA; ABD AND BACK	2020-11-19 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522533; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Immune system disorders/ Smoke sensitivity/ SMOKE ALLERGY SYMPTOMS, WHEEZING, ITCHY THROAT	2020-09-10 (9)/ 2020-09-20 (19)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522536; Age (years): 65; Sex: F; Race: OTHER: (b) (6)							
Injury, poisoning and procedural complications/ Muscle strain/ BACK STRAIN	2020-10-19 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3522583; Age (years): 33; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ CHEST CONGESTION	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3522583; Age (years): 33; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	2020-11-01 (24)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522626; Age (years): 71; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-19 (13)/ 2020-10-19 (13)	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522642; Age (years): 55; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-10-01 12:00 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522656; Age (years): 26; Sex: F; Race: WHITE							
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	2020-10-10 12:00 (2)/ 2020-10-10 12:10 (2)	Yes/ Yes/ No	2	No	NR/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3522674; Age (years): 66; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ LEFT ARM CONTUSION	2020-10-09 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3532016; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Respiratory disorder/ RESPIRATORY ILLNESS	2020-10-05 (22)/ 2020-10-10 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532020; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ulnar nerve injury/ ULNAR NERVE IRRITATION	2020-08-16 (4)/ 2020-10-15 (64)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532047; Age (years): 33; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-08-20 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3532051; Age (years): 76; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT HIP PAIN	2020-09-27 (13)/ 2020-11-03 (50)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-11-05 (52)/ 2020-11-10 (57)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3532063; Age (years): 70; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Femur fracture/ FRACTURED FEMUR	2020-10-28 (43)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-28/ 2020-11-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532074; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ RIGHT SHOULDER STRAIN	2020-09-03 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3532080; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Gait disturbance/ UNSTEADY GAIT	2020-09-08 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Renal and urinary disorders/ Urge incontinence/ WORSENING OF URGE INCONTINENCE	2020-09-11 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532080; Age (years): 68; Sex: M; Race: WHITE							
Renal and urinary disorders/ Urinary retention/ BLADDER NOT EMPTYING	2020-10-06 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3532087; Age (years): 85; Sex: M; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS, CONGESTION, RUNNY NNOSE, SORE THROAT, COUGH	2020-11-02 (43)/ 2020-11-15 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532106; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Folliculitis/ HOT TUB FOLLICULITIS (RASH)	2020-09-13 (24)/ 2020-10-28 (69)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532134; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION TO RIGHT HAND	2020-10-23 (31)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532141; Age (years): 69; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ SKIN CANCER, BASAL CELL CARCINOMA, FACE	2020-09-25 (3)/ 2020-10-14 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3532158; Age (years): 75; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Penile cancer/ CANCEROUS TUMOR-PENIS	2020-11-16 (55)/ Ongoing	Yes/ Yes/ No	3	Yes/2	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3532170; Age (years): 66; Sex: F; Race: WHITE							
Cardiac disorders/ Acute myocardial infarction/ ACUTE MYOCARDIAL INFARTION	2020-09-06 (11)/ 2020-10-06 (41)	Yes/ Yes/ No	4	Yes/3 (2020-09-06/ 2020-10-06)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532170; Age (years): 66; Sex: F; Race: WHITE							
Cardiac disorders/ Ventricular fibrillation/ VENTRICULAR FIBRILLATION- INTERMEDIATE	2020-09-08 (13)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-12 (17)/ 2020-10-09 (44)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural anxiety/ ANXIETY POST CABG	2020-10-06 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Infected skin ulcer/ INFECTED WOUND- BEDSORE	2020-11-13 (79)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532187; Age (years): 77; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ WORSENING PROSTATIC HYPERTROPHY	2020-10-15 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3532189; Age (years): 76; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ RED SMALL AREA ON FACE	2020-09-15 (16)/ 2020-09-22 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532201; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING LUMBAR BACK PAIN	2020-10-15 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532210; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	2020-11-14 (47)/ 2020-11-17 (50)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-11-14 (47)/ 2020-11-20 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532222; Age (years): 66; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Eye injury/ EYE INJURY	2020-09-11 (10)/ 2020-09-16 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532232; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS #9	2020-10-16 (16)/ 2020-10-23 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532237; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Otitis externa/ OTIS EXTERNA	2020-09-15 (13)/ 2020-09-21 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532244; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Gingivitis/ WORSENING GINGIVITIS	2020-11-04 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3532246; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-10-25 (20)/ 2020-11-10 (36)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532251; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Exposure to SARS-CoV-2/ EXPOSURE TO COVID-19-COVID-19 TESTING	2020-10-30 (25)/ 2020-10-30 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532258; Age (years): 46; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-23 (17)/ 2020-11-06 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532273; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Sciatica/ WORSENING OF SCIATICA	2020-10-22 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Herpes zoster/ SHINGLES OUTBREAK	2020-11-08 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3532276; Age (years): 77; Sex: F; Race: WHITE							
Surgical and medical procedures/ Tooth repair/ REPAIR OF CROWN ON TOOTH	2020-10-28 (21)/ 2020-10-28 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542015; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-09-30 (16)/ 2020-10-06 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542019; Age (years): 70; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	2020-09-25 (11)/ 2020-10-01 (17)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542030; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS	2020-08-29 (10)/ 2020-09-07 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Tooth fracture/ TOOTH CROWN CRACKING	2020-09-01 (13)/ 2020-09-23 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542030; Age (years): 56; Sex: F; Race: WHITE							
Surgical and medical procedures/ Tooth repair/ DENTAL FILLING REPLACEMENT	2020-09-29 (6)/ 2020-09-29 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Toothache/ TOOTH PAIN	2020-10-19 (26)/ 2020-10-19 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Surgical and medical procedures/ Tooth repair/ TOOTH CROWN REPAIR	2020-10-19 (26)/ 2020-10-19 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542031; Age (years): 84; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Head injury/ HEAD INJURY	2020-09-17 (1)/ 2020-09-23 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542042; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Otitis externa/ LEFT OTITIS EXTERNA	2020-10-15 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542043; Age (years): 26; Sex: F; Race: MULTIPLE: (b) (6)							
Reproductive system and breast disorders/ Cervical dysplasia/ LOW GRADE SQUAMOUS INTRAEPITHELIAL LESION OF CERVIX	2020-10-06 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3542047; Age (years): 74; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Amnesia/ WORSENING MEMORY LOSS	2020-11-10 (54)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542053; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN, LOWER	2020-09-25 (5)/ 2020-10-02 (12)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542059; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-10 (19)/ 2020-10-23 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542081; Age (years): 45; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Skin and subcutaneous tissue disorders/ Acne/ ACNE	2020-10-15 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542088; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-28 (7)/ 2020-10-03 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542090; Age (years): 65; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ POLYARTHRALGIAS	2020-09-03 (7)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542100; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-08 (11)/ 2020-10-10 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-08 (11)/ 2020-10-10 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542117; Age (years): 72; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Inguinal hernia/ RIGHT GROIN PAIN SECONDARY TO INGUINAL HERNIA	2020-10-15 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3542126; Age (years): 65; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Skin infection/ SKIN INFECTION (RIGHT LATERAL CHEST)	2020-09-19 (19)/ 2020-10-10 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542153; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-14 (37)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542156; Age (years): 36; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ PRURITUS AT INJECTION SITE	2020-10-06 10:32 (1)/ 2020-10-06 17:00 (1)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542168; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Anxiety/ ANXIETY EXACERBATION	2020-09-10 (7)/ 2020-09-18 (15)	Yes/ Yes/ No	4	Yes/3 (2020-09-10/ 2020-09-18)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LOWER LEG PAIN	2020-09-18 (15)/ 2020-09-19 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Anxiety/ ANXIETY EXACERBATION	2020-09-19 (16)/ 2020-09-23 (20)	Yes/ Yes/ No	3	Yes/3 (2020-09-19/ 2020-09-23)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542168; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Depression/ DEPRESSION EXACERBATION	2020-09-19 (16)/ 2020-09-23 (20)	Yes/ Yes/ No	3	Yes/3 (2020-09-19/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542191; Age (years): 71; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Cerumen impaction/ RIGHT CERUMEN IMPACTION	2020-10-31 (25)/ 2020-11-01 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542199; Age (years): 66; Sex: M; Race: WHITE							
Renal and urinary disorders/ Renal mass/ RENAL MASS	2020-10-20 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3542218; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ ACUTE PHARYNGITIS DUE TO GROUP A STREPTOCOCCUS	2020-10-05 (22)/ 2020-10-09 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542218; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-21 (10)/ 2020-10-30 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542230; Age (years): 57; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth injury/ TOOTH DAMAGE	2020-09-21 (7)/ 2020-09-28 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3542236; Age (years): 74; Sex: F; Race: WHITE							
Investigations/ Blood cholesterol increased/ ELEVATED CHOLESTEROL	2020-10-11 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542254; Age (years): 48; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-06 (20)/ 2020-10-12 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542261; Age (years): 68; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-30 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542277; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-10-05 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542294; Age (years): 31; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ ANKLE SPRAIN	2020-10-22 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542342; Age (years): 44; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus pain/ SINUS PAIN	2020-10-26 (13)/ 2020-11-01 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542348; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-24 (9)/ 2020-10-29 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552002; Age (years): 40; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-18 (12)/ 2020-09-25 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: ONGOING ANOSMIA
Subject ID: US3552007; Age (years): 35; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Haematochezia/ BLOOD IN STOOL	2020-11-07 (59)/ 2020-11-09 (61)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552040; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Eye infection/ EYE INFECTION	2020-09-17 (4)/ 2020-10-04 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552048; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-05 (56)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Ear and labyrinth disorders/ Ear pain/ RIGHT EAR PAIN	2020-11-14 (65)/ 2020-11-22 (73)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552076; Age (years): 37; Sex: M; Race: WHITE							
Psychiatric disorders/ Bipolar disorder/ BIPOLAR DISORDER	2020-09-09 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552079; Age (years): 66; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-09-24 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3552087; Age (years): 65; Sex: M; Race: WHITE							
Cardiac disorders/ Palpitations/ INCREASED HEART PALPITATIONS	2020-09-12 (25)/ 2020-10-16 (59)	Yes/ Yes/ No	2	No	R/ R	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552092; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-05 (18)/ 2020-09-17 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552107; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-21 (33)/ 2020-09-24 (36)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552107; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-21 (33)/ 2020-09-25 (37)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-22 (34)/ 2020-09-27 (39)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-26 (38)/ 2020-09-26 (38)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552111; Age (years): 66; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	2020-09-19 (5)/ 2020-09-21 (7)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552111; Age (years): 66; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-19 (5)/ 2020-09-21 (7)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 (5)/ 2020-09-23 (9)	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-19 (5)/ 2020-09-23 (9)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552111; Age (years): 66; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Chest discomfort/ GENERAL NON-CARDIAC CHEST TIGHTNESS	2020-09-19 (5)/ 2020-09-25 (11)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-19 (5)/ 2020-09-25 (11)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-23 (9)/ 2020-09-23 (9)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552111; Age (years): 66; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-13 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-13 (29)/ 2020-11-06 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Epistaxis/ NOSE BLEED	2020-10-14 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-10-15 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552111; Age (years): 66; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Nervous system disorders/ Anosmia/ LOSS OF SMELL	2020-10-15 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-15 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-15 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552111; Age (years): 66; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
General disorders and administration site conditions/ Chest discomfort/ GENERAL, NON-CARDIAC, INTERMITTENT CHEST TIGHTNESS	2020-10-19 (35)/ 2020-11-06 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552132; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Fungal skin infection/ FUNGAL INFECTION ON HANDS	2020-08-28 (8)/ 2020-09-13 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552140; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Eye disorders/ Retinal detachment/ RETINAL DETACHMENT OF LEFT EYE	2020-09-08 (18)/ 2020-09-12 (22)	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3552140; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Eye disorders/ Retinal tear/ HORSESHOE TEAR OF RIGHT EYE	2020-10-01 (41)/ 2020-10-06 (46)	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3552143; Age (years): 46; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Oral pain/ ORAL PAIN	2020-10-06 (18)/ 2020-10-08 (20)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3552146; Age (years): 44; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-23 (33)/ 2020-10-29 (39)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3552146; Age (years): 44; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-26 (36)/ 2020-10-26 (36)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552218; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 (22)/ 2020-10-19 (25)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-16 (22)/ 2020-10-19 (25)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-16 (22)/ 2020-10-19 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE							
Cardiac disorders/ Acute myocardial infarction/ NON-ST ELEVATED MYOCARDIAL INFARCTION	2020-09-26 (29)/ 2020-09-26 (29)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hypomagnesaemia/ HYPOMAGNESIA	2020-09-26 (29)/ 2020-10-08 (41)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-09-26 (29)/ 2020-10-08 (41)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ PAROXYSMAL ATRIAL FIBRILLATION	2020-09-26 (29)/ 2020-10-30 (63)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: 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.
Respiratory, thoracic and mediastinal disorders/ Organising pneumonia/ CRYPTOGENIC ORGANIZING PNEUMONIA	2020-09-26 (29)/ 2020-11-19 (83)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-27 (30)/ 2020-09-27 (30)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE	2020-09-28 (31)/ 2020-11-19 (83)	Yes/ Yes/ No	4	Yes/3 (2020-09-26/ 2020-10-08)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552255; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Limb mass/ LUMP ON RIGHT FOREARM	2020-11-13 (47)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3552269; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-10 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552273; Age (years): 52; Sex: M; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-09-01 14:07 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-09-01 14:07 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3552275; Age (years): 47; Sex: M; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-11 (11)/ 2020-09-17 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-11 (11)/ 2020-09-18 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552275; Age (years): 47; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-17 (17)/ 2020-09-17 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552283; Age (years): 53; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-02 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3552309; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ Eye infection/ INFECTION RIGHT EYE	2020-09-26 (24)/ 2020-10-04 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552312; Age (years): 55; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-07 (7)/ 2020-11-19 (50)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552316; Age (years): 22; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-10 (10)/ 2020-10-18 (18)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-10 (10)/ 2020-10-21 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-10 (10)/ 2020-10-21 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552316; Age (years): 22; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 (16)/ 2020-10-17 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-16 (16)/ 2020-10-21 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552319; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-09-12 (10)/ 2020-09-19 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552331; Age (years): 44; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-09-15 (12)/ 2020-10-01 (28)	Yes/ Yes/ No	4	Yes/3 (2020-09-16/ 2020-09-21)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552341; Age (years): 34; Sex: M; Race: OTHER: (b) (6)							
Injury, poisoning and procedural complications/ Stress fracture/ STRESS FRACTURE LEFT FOOT	2020-09-20 (16)/ 2020-10-22 (48)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552360; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-14 (9)/ 2020-10-17 (12)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552399; Age (years): 58; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS	2020-10-08 18:00 (1)/ 2020-11-09 (33)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3552402; Age (years): 65; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-14 08:00 (1)/ 2020-10-31 (19)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552417; Age (years): 72; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ FRACTURE OF 5TH METATARSAL, LEFT FOOT	2020-10-13 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3552424; Age (years): 57; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ WORSENING BENIGN PROSTATIC HYPERPLASIA	2020-11-05 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Hordeolum/ RIGHT EYE STY	2020-11-05 (29)/ 2020-11-12 (36)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552424; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Oedema peripheral/ LEFT LEG EDEMA	2020-11-13 (37)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3552444; Age (years): 74; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ WORSENING ATRIAL FIBRILLATION ARRHYTHMIA	2020-10-01 (16)/ 2020-10-16 (31)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552462; Age (years): 52; Sex: F; Race: MULTIPLE:						(b) (6)	
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-21 (8)/ 2020-10-26 (13)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552468; Age (years): 65; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-16 12:27 (1)/ 2020-10-29 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552484; Age (years): 40; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-28 (10)/ 2020-11-01 (14)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552518; Age (years): 32; Sex: M; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-14 (13)/ 2020-11-16 (15)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552530; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED URTICARIAL RASH	2020-10-18 (5)/ 2020-11-13 (31)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562023; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Precancerous condition/ PRE-CANCEROUS LESION UPPER BACK	2020-09-17 (9)/ 2020-09-17 (9)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3562117; Age (years): 56; Sex: M; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-09-11 (8)/ 2020-09-17 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3562120; Age (years): 52; Sex: M; Race: ASIAN							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-10-16 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3562122; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-09 (2)/ 2020-09-16 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562132; Age (years): 75; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS BILATERAL HANDS	2020-10-01 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3562150; Age (years): 57; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF LEFT KNEE PAIN	2020-09-29 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3562161; Age (years): 43; Sex: F; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL HIP PAIN	2020-10-07 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562161; Age (years): 43; Sex: F; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL KNEE PAIN	2020-10-07 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3562168; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Tinea versicolour/ TINEA VERSICOLOR	2020-09-25 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3562199; Age (years): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADEMOPATHY CERVICAL CONTRALATERAL	2020-10-08 (11)/ 2020-10-09 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572022; Age (years): 48; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-11-11 (85)/ 2020-11-14 (88)	Yes/ Yes/ Yes	1	No		/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3572022; Age (years): 48; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-11-11 (85)/ 2020-11-20 (94)	Yes/ Yes/ Yes	1	No		/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-11 (85)/ 2020-11-20 (94)	Yes/ Yes/ Yes	1	No		/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572023; Age (years): 39; Sex: F; Race: WHITE							
Investigations/ Blood glucose increased/ ELEVATED BLOOD GLUCOSE	2020-10-08 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3572028; Age (years): 52; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ SEVERE ABDOMINAL CRAMPING	2020-10-09 (52)/ 2020-10-11 (54)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3572055; Age (years): 45; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ SLICED INDEX FINGER ON LEFT HAND UNABLE TO STOP BLEEDING AT HOME	2020-08-24 (4)/ 2020-08-24 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572059; Age (years): 34; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GI REFLUX	2020-10-27 (33)/ Ongoing	Yes/ Yes/ No	1	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3572078; Age (years): 22; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION ON LEFT PALM	2020-09-12 (20)/ 2020-09-12 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572090; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ HUMAN RHINO VIRUS	2020-11-05 (45)/ Ongoing	Yes/ Yes/ No	2	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3572101; Age (years): 69; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-05 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-05 (12)/ Ongoing	Yes/ Yes/ No	2	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3572104; Age (years): 50; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-10-05 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-05 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572122; Age (years): 51; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain lower/ PAIN LLQ (ABDOMEN)	2020-09-03 (8)/ 2020-10-24 (59)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572124; Age (years): 45; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ankle fracture/ BROKEN RIGHT ANKLE	2020-10-14 (20)/ Ongoing	Yes/ Yes/ Yes	1			/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3572134; Age (years): 48; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-11-09 (42)/ 2020-11-13 (46)	Yes/ Yes/ No	3	Yes/3 (2020-11-09/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3572139; Age (years): 35; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-02 (5)/ 2020-10-14 (17)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572139; Age (years): 35; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-10-02 (5)/ 2020-10-22 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572167; Age (years): 43; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH ON BOTH LEGS - ON CALF AND SHINS BILATERAL	2020-10-20 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3572176; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-14 (13)/ 2020-10-15 (14)	Yes/ Yes/ No	1	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-14 (13)/ 2020-10-23 (22)	Yes/ Yes/ No	2	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572199; Age (years): 35; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Superficial injury of eye/ SCRATCH TO RIGHT EYE	2020-10-02 (29)/ 2020-10-12 (39)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572219; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-24 (18)/ 2020-10-26 (20)	Yes/ Yes/ No	2	No		/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572239; Age (years): 70; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	2020-09-29 (21)/ Ongoing	Yes/ Yes/ No	1	No		/ NONE	RECOVERING/ RESOLVING
Subject ID: US3572240; Age (years): 81; Sex: F; Race: WHITE							
Eye disorders/ Dry eye/ DRY EYE	2020-09-25 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572385; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-24 (16)/ 2020-10-29 (21)	Yes/ Yes/ No	1	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572387; Age (years): 39; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-20 (11)/ Ongoing	Yes/ Yes/ No	1	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3582023; Age (years): 46; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Paraesthesia/ TINGLING IN BILATERAL FEET	2020-09-14 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3582033; Age (years): 76; Sex: M; Race: MULTIPLE: (b) (6)							
Ear and labyrinth disorders/ Ear pain/ RIGHT EAR - OTALGIA	2020-09-03 (11)/ 2020-09-04 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582055; Age (years): 31; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-08-27 06:00 (1)/ 2020-08-28 20:00 (3)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3582080; Age (years): 37; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-13 (13)/ 2020-09-15 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-14 (14)/ 2020-09-15 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582120; Age (years): 44; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ WORSENING HYPERLIPIDEMIA	2020-09-22 (14)/	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582129; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-11-17 (41)/	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	
Subject ID: US3582130; Age (years): 26; Sex: M; Race: MULTIPLE:						(b) (6)	
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 (10)/ 2020-09-26 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582154; Age (years): 29; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Noninfective gingivitis/ GINGIVAL INFLAMMATION DUE TO BRACKET OF BRACES. RIGHT UPPER TOOTH (#3)	2020-11-02 (20)/ 2020-11-08 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3592014; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-06 (64)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592084; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-06 (62)/ Ongoing	Yes/ Yes/ No		No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592117; Age (years): 33; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-05 (59)/ 2020-11-14 (68)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3592127; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-11 (63)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592132; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 SYMPTOMATIC	2020-10-25 (47)/ 2020-11-01 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592139; Age (years): 50; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION	2020-09-08 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592157; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-09-01 (19)/ 2020-09-18 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3592161; Age (years): 33; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-30 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592187; Age (years): 74; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Bladder neoplasm/ BLADDER TUMOR	2020-08-22 (8)/ 2020-09-08 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3592189; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-10-31 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592199; Age (years): 18; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION TO HAND	2020-08-21 (6)/ 2020-08-31 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION TO SCALP	2020-08-21 (6)/ 2020-08-31 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592224; Age (years): 20; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-10-07 (24)/ 2020-10-07 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-07 (24)/ 2020-10-07 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 (24)/ 2020-10-08 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592224; Age (years): 20; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-07 (24)/ 2020-10-09 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3592229; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-22 (5)/ 2020-08-26 (9)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602015; Age (years): 44; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-21 (19)/ 2020-09-22 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602029; Age (years): 24; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Stress fracture/ STRESS FRACTURE OF RLE - REPORTED IN V3D57	2020-11-02 (22)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN							
General disorders and administration site conditions/ Swelling face/ SWELLING TO THE RIGHT SIDE OF THE FACE	2020-09-17 (7)/ 2020-09-27 (17)	Yes/ Yes/ No	2	Yes/6	R/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ TINGLING ON RIGHT SIDE OF FACE	2020-09-17 (7)/ 2020-09-28 (18)	Yes/ Yes/ No	2	Yes/6	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Immunisation anxiety related reaction/ ANXIETY RELATED TO THE VACCINE	2020-09-17 (7)/ 2020-10-07 (27)	Yes/ Yes/ No	2	Yes/6	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN							
Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ LEFT SIDED PLEURITIC CHEST PAIN	2020-09-27 (17)/ 2020-09-29 (19)	Yes/ Yes/ No	1	Yes/6	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Feeling hot/ LEFT SIDED CHEST WALL WARMTH	2020-10-06 (26)/ 2020-10-16 (36)	Yes/ Yes/ No	2	Yes/4	R/ R	DOSE DELAYED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Nervous system disorders/ Paraesthesia/ LEFT SIDED TINGLING	2020-10-06 (26)/ 2020-10-16 (36)	Yes/ Yes/ No	2	Yes/4/6	R/ R	DOSE DELAYED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602034; Age (years): 38; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Night sweats/ SWEATING AT NIGHTS	2020-10-26 (18)/ 2020-10-31 (23)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Eye disorders/ Swelling of eyelid/ BILATERAL EYELID PUFFINESS	2020-10-27 (19)/ 2020-10-29 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Eye disorders/ Swelling of eyelid/ BILATERAL EYELID SWELLING	2020-10-27 (19)/ 2020-10-29 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602038; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID - 19	2020-11-05 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602051; Age (years): 52; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ RIB PAIN (BILATERAL) PAIN SCALE: 8/10	2020-10-27 (14)/ 2020-10-31 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Vascular disorders/ Aortic stenosis/ WORSENING OF AORTIC STENOSIS	2020-10-28 (15)/ 2020-11-02 (20)	Yes/ Yes/ No	4	Yes/3 (2020-10-29/ 2020-11-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: PT WITH OPEN SURGERY AND POST OP RECOVERY ONGOING
Injury, poisoning and procedural complications/ Procedural haemorrhage/ INCREASED BLEEDING INTRA OPERATIVE TIME	2020-10-29 (16)/ 2020-10-29 (16)	Yes/ Yes/ No	4	Yes/4	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602052; Age (years): 47; Sex: F; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ ARM PAIN (LEFT ARM)	2020-09-27 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Back pain/ UPPER BACK PAIN	2020-09-28 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Joint range of motion decreased/ LIMITATIONS IN LEFT ARM ROM	2020-09-28 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602052; Age (years): 47; Sex: F; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-09-28 (12)/ 2020-09-30 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3602111; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-10-24 (26)/ 2020-11-23 (56)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602149; Age (years): 28; Sex: M; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATING	2020-10-30 (16)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3612010; Age (years): 67; Sex: M; Race: WHITE							
Vascular disorders/ Aortic aneurysm/ ABDOMINAL AORTIC ANEURYSM (3CM)	2020-10-16 (17)/ Ongoing	Yes/ Yes/ No	1	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3612010; Age (years): 67; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	2020-10-21 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3612040; Age (years): 51; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Prostatitis/ PROSTATITIS	2020-10-29 (16)/ 2020-11-08 (26)	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622002; Age (years): 83; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal discomfort/ UPSET STOMACH	2020-08-20 (11)/ 2020-08-27 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-20 (11)/ 2020-08-28 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622002; Age (years): 83; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-20 (11)/ 2020-08-28 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622011; Age (years): 80; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Skin cancer/ BACK SKIN CANCER	2020-10-14 (37)/ 2020-10-14 (37)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622012; Age (years): 23; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-08-29 (19)/ 2020-09-04 (25)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622020; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-10-16 (37)/ 2020-10-17 (38)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622031; Age (years): 56; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-21 (8)/ 2020-08-25 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-08-21 (8)/ 2020-08-25 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Conjunctivitis/ MILD CONJUNCTIVITIS BILATERAL	2020-08-22 (9)/ 2020-08-25 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-22 (9)/ 2020-08-25 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622048; Age (years): 56; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Surgical and medical procedures/ Cataract operation/ CATARACT SURGERY RIGHT EYE	2020-10-02 (16)/ 2020-10-02 (16)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Surgical and medical procedures/ Cataract operation/ CATARACT SURGERY LEFT EYE	2020-10-16 (30)/ 2020-10-16 (30)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622061; Age (years): 51; Sex: F; Race: ASIAN							
Ear and labyrinth disorders/ Tinnitus/ TINITUS (BILATERAL)	2020-08-24 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622067; Age (years): 70; Sex: F; Race: WHITE							
Eye disorders/ Vision blurred/ INTERMITTENT BLURRED VISION	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622067; Age (years): 70; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622067; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	2020-11-11 (52)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622104; Age (years): 49; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ FLU VACCINE INJECTION SITE SORENESS	2020-10-06 (9)/ 2020-10-08 (11)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622124; Age (years): 53; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-11 (13)/ 2020-10-18 (20)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622124; Age (years): 53; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-11 (13)/ 2020-10-18 (20)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-11 (13)/ 2020-10-18 (20)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sneezing/ SNEEZING	2020-10-11 (13)/ 2020-10-18 (20)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622124; Age (years): 53; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-12 (14)/ 2020-10-18 (20)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 (17)/ 2020-10-18 (20)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622132; Age (years): 44; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastritis/ GASTRITIS	2020-10-07 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3622150; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-21 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622150; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-21 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622161; Age (years): 65; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-21 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-21 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622161; Age (years): 65; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-21 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-21 (20)/ 2020-10-21 (20)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-22 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3622161; Age (years): 65; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-10-22 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-22 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-22 (21)/ 2020-10-22 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-22 (21)/ 2020-10-26 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622191; Age (years): 20; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gingival swelling/ LEFT LOWER JAW GUM SWELLING/PUS (BEHIND WISDOM TOOTH)	2020-10-27 (14)/ 2020-11-11 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622194; Age (years): 20; Sex: F; Race: WHITE							
Infections and infestations/ Tonsillitis/ TONSILITIS	2020-10-12 (27)/ 2020-10-21 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622215; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ Hordeolum/ RIGHT EYE STYE	2020-10-03 (12)/ 2020-10-03 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622216; Age (years): 51; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Middle ear effusion/ WATER IN LEFT EAR	2020-10-20 (1)/ 2020-10-21 (2)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3622246; Age (years): 56; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ LEFT ARM INJURY AFTER FALL	2020-10-23 (24)/ 2020-11-03 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622249; Age (years): 57; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ RIGHT CALCANEUS FRACTURE	2020-10-30 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622257; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-11-05 (2)/ 2020-11-16 (13)	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3622271; Age (years): 49; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ CERVICAL DISC HERNIATION C5 AND C7	2020-10-17 (5)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Sciatica/ SCIATICA	2020-10-17 (5)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622282; Age (years): 51; Sex: F; Race: WHITE							
Surgical and medical procedures/ Foot operation/ FOOT/ANKLE SURGERY	2020-11-05 (16)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-05/)	NR/ NR	DOSE NOT CHANGED/	UNKNOWN

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Subject ID: US3632002; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Rash papular/ PAPULAR RASH IN BOTH EARS (NON-URTICARIAL)	2020-09-11 (23)/ 2020-09-20 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632004; Age (years): 61; Sex: F; Race: WHITE							
Eye disorders/ Blepharitis/ BLETHORITIS (RIGHT EYE)	2020-09-22 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-22 (5)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3632007; Age (years): 69; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Diabetes mellitus/ TYPE II DIABETES WORSENING	2020-09-04 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632022; Age (years): 68; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Leiomyosarcoma metastatic/ METASTATIC LEIOMYOSARCOMA	2020-11-20 (57)/ Ongoing	Yes/ Yes/ No	4	Yes/2	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632025; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Conjunctivitis/ CONJUNCTIVITIS	2020-11-01 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3632032; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertensive emergency/ HYPERTENSIVE EMERGENCY	2020-09-16 14:15 (1)/ 2020-09-18 16:27 (3)	Yes/ Yes/ No	4	Yes/2	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632033; Age (years): 75; Sex: M; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS ON SECOND TOE ON LEFT FOOT	2020-09-27 (24)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3632039; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod sting/ BEE STING LEFT FOOT, SWELLING AND ITCHING	2020-09-05 (4)/ 2020-09-09 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632054; Age (years): 32; Sex: F; Race: WHITE							
Surgical and medical procedures/ Endodontic procedure/ ROOT CANAL	2020-10-21 (16)/ 2020-10-21 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632074; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Acute sinusitis/ ACUTE SINUSITIS	2020-10-02 (22)/ 2020-10-06 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632080; Age (years): 40; Sex: M; Race: OTHER: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY	2020-10-18 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3632090; Age (years): 71; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASM	2020-09-17 00:00 (1)/ 2020-09-24 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632091; Age (years): 29; Sex: M; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-10-27 (15)/ 2020-11-09 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632094; Age (years): 39; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID	2020-10-29 (18)/ 2020-11-07 (27)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632117; Age (years): 45; Sex: F; Race: MULTIPLE: (b) (6)							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-11-03 08:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Depression/ DEPRESSION	2020-11-03 08:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFICIENCY	2020-11-03 12:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3632126; Age (years): 22; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Genital herpes/ GENITAL HERPES	2020-10-18 (6)/ 2020-11-09 (28)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632127; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Foot fracture/ FRACTURED, 4TH, RIGHT TOE.	2020-11-07 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Social circumstances/ Sexual abuse/ SEXUAL ASSAULT	2020-11-07 (26)/ 2020-11-07 (26)	Yes/ Yes/ No	4	Yes/2/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632129; Age (years): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-12 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Rales/ FINE CRACKLES ON RIGHT LUNG FIELD	2020-11-12 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632140; Age (years): 33; Sex: M; Race: MULTIPLE:						(b) (6)	
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-11-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGHING	2020-11-02 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASM IN LOWER BACK	2020-11-12 (25)/ 2020-11-16 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632154; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ TWO SMALL BILATERAL PLEURAL EFFUSIONS	2020-11-05 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3642018; Age (years): 74; Sex: M; Race: WHITE							
Nervous system disorders/ Neuropathy peripheral/ NEUROPATHY	/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3642023; Age (years): 74; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-15 (22)/ 2020-10-16 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3642035; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Flank pain/ LOWER BACK LEFT FLANK PAIN	2020-08-31 (4)/ 2020-09-01 (5)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642065; Age (years): 75; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastritis/ GASTRITIS	2020-09-05 (6)/ 2020-09-06 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3642074; Age (years): 36; Sex: M; Race: NOT REPORTED							
Infections and infestations/ COVID-19/ COVID-19	2020-11-12 (45)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3642131; Age (years): 73; Sex: M; Race: WHITE							
Nervous system disorders/ Presyncope/ VASOVAGAL REACTION TO BLOOD DRAW	2020-10-03 09:40 (28)/ 2020-10-03 10:13 (28)	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Presyncope/ VASOVAGAL REACTION TO BLOOD DRAW	2020-11-05 (34)/ 2020-11-05 (34)	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3642212; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Tonsillitis/ TONSILITIS RESULTING FROM TONSIL STONES	2020-10-16 (5)/ 2020-10-19 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3642229; Age (years): 46; Sex: M; Race: UNKNOWN							
Infections and infestations/ COVID-19/ COVID-19	2020-11-14 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3642236; Age (years): 29; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ FAINTING	2020-10-31 (13)/ 2020-10-31 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652004; Age (years): 67; Sex: M; Race: OTHER: PATIENT IDENTIFIED RACE AS OTHER							
Gastrointestinal disorders/ Constipation/ CONSTIPATION	2020-09-06 (6)/ 2020-09-10 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652006; Age (years): 70; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Umbilical hernia/ HERNIA (UMBILICAL)	2020-09-21 (19)/ 2020-10-16 (44)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652039; Age (years): 33; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 (SARS-COV-2 CONFIRMED 10/27/2020)	2020-10-25 (27)/ 2020-11-03 (36)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662009; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Ear and labyrinth disorders/ Ear canal erythema/ RIGHT EAR CANAL ERYTHEMA	2020-10-06 09:20 (28)/ 2020-10-13 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662010; Age (years): 65; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-22 (13)/ 2020-09-24 (15)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662019; Age (years): 65; Sex: M; Race: WHITE							
Eye disorders/ Periorbital swelling/ PERI-ORBITAL SWELLING	2020-09-10 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Otitis media acute/ ACUTE SEROUS OTITIS MEDIA, BILATERAL	2020-09-10 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662025; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-25 (8)/ 2020-10-01 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chest pain/ LEFT-SIDED CHEST PAIN	2020-10-25 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3662025; Age (years): 68; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM PAIN	2020-10-25 (7)/ 2020-10-28 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Pelvic discomfort/ PELVIC PRESSURE	2020-10-25 (7)/ 2020-10-28 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-26 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ RIGHT CHEST WALL PAIN	2020-10-26 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3662033; Age (years): 67; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-07 (7)/ 2020-09-08 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Appendicitis/ ACUTE APPENDICITIS	2020-09-08 (8)/ 2020-09-09 (9)	Yes/ Yes/ No	3	Yes/3 (2020-09-08/ 2020-09-10)/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-08 (8)/ 2020-09-10 (10)	Yes/ Yes/ No	3	Yes/3 (2020-09-08/ 2020-09-10)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3662033; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ ABDOMINAL PAIN POST-OP	2020-09-11 (11)/ 2020-09-17 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-10-08 (10)/ 2020-10-12 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Upper-airway cough syndrome/ POST NASAL DRIP	2020-10-08 (10)/ 2020-10-12 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3662039; Age (years): 76; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT LEG PAIN	2020-10-09 (25)/ 2020-10-12 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Excessive cerumen production/ RIGHT EAR INCREASED CERUMEN	2020-10-13 (1)/ 2020-11-17 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662041; Age (years): 74; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT THIGH PAIN	2020-09-15 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662045; Age (years): 58; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION IN RIGHT THUMB	2020-10-07 (7)/ 2020-10-07 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Skin laceration/ PAIN IN RIGHT THUMB FROM LACERATION	2020-10-07 (7)/ 2020-10-15 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Localised infection/ INFECTION IN RIGHT THUMB	2020-10-10 (10)/ 2020-11-05 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662048; Age (years): 28; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-20 (19)/ 2020-10-20 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662048; Age (years): 28; Sex: F; Race: WHITE							
Nervous system disorders/ Sinus headache/ SINUS HEADACHE	2020-10-20 (19)/ 2020-10-20 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662053; Age (years): 51; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Benign neoplasm of skin/ BENIGN NEOPLASM SKIN-OTHER AND UNSPECIFIED PART OF FACE	2020-09-30 (27)/ 2020-09-30 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662062; Age (years): 55; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF RIGHT KNEE PAIN	2020-09-17 (9)/ 2020-09-30 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662065; Age (years): 73; Sex: M; Race: WHITE							
Eye disorders/ Retinal detachment/ RETINAL DETACHMENT WITH RETINAL BREAK	2020-10-07 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662066; Age (years): 73; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ BROKEN TOOTH	2020-10-03 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Toothache/ TOOTH PAIN	2020-10-05 (27)/ 2020-10-12 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662071; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Axillary mass/ PEA SIZE SWOLLEN LUMP IN LEFT UNDERARM	2020-10-15 (4)/ 2020-10-27 (16)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662071; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Axillary mass/ REDNESS AT SWOLLEN LUMP IN LEFT UNDERARM	2020-10-15 (4)/ 2020-10-27 (16)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Axillary mass/ WARMTH AT SWOLLEN LUMP IN LEFT UNDERARM	2020-10-15 (4)/ 2020-10-27 (16)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ UNDERARM RASH	2020-10-15 (4)/ 2020-10-29 (18)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662088; Age (years): 52; Sex: F; Race: ASIAN							
Investigations/ Biopsy endometrium/ ENDOMETRIAL BIOPSY	2020-11-20 (38)/ 2020-11-20 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3662090; Age (years): 69; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-28 (15)/ 2020-10-12 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ ACUTE UPPER RESPIRATORY INFECTION	2020-10-05 (22)/ 2020-10-14 (31)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662093; Age (years): 82; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal tenderness/ EPIGASTRIC TENDERNESS ON PALPATION	2020-11-16 (36)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662094; Age (years): 81; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ REDNESS, 2ND FORM LAST TOE ON RIGHT FOOT	2020-09-25 (12)/ 2020-09-28 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Peripheral swelling/ SWELLING, 2ND FROM LAST TOE ON RIGHT FOOT	2020-09-25 (12)/ 2020-10-10 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662094; Age (years): 81; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN, 2ND FROM LAST TOE ON RIGHT FOOT	2020-09-25 (12)/ 2020-10-10 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Gout/ GOUT-TOE	2020-09-30 (17)/ 2020-10-10 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ HYPERTROPHY OF PROSTATE	2020-10-18 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Dysuria/ DYSURIA	2020-10-23 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662094; Age (years): 81; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI, SITE NOT SPECIFIED	2020-10-23 (12)/ 2020-11-05 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Prostatitis/ ACUTE PROSTATITIS	2020-10-23 (12)/ 2020-11-05 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662095; Age (years): 46; Sex: M; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ CHEST CONGESTION	2020-10-20 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-20 (6)/ 2020-10-21 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662095; Age (years): 46; Sex: M; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Painful respiration/ SLIGHT CHEST PRESSURE. NON CARDIAC, RESPIRATORY PAIN.	2020-10-21 (7)/ 2020-10-21 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chest discomfort/ IRREGULAR CHEST PRESSURE	2020-10-27 (13)/ 2020-10-29 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Ear canal erythema/ BILATERAL ERYTHEMA OF EAR CANAL	2020-11-03 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662095; Age (years): 46; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Sinusitis/ PAN SINUSITIS	2020-11-03 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pharyngeal erythema/ ERYTHEMA OF THROAT	2020-11-03 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662098; Age (years): 32; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-22 (11)/ 2020-11-06 (26)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Otitis externa/ BILATERAL OTITIS EXTERNA	2020-10-28 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662103; Age (years): 65; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pharyngeal erythema/ DIFFUSE PHARYNX ERYTHEMA	2020-11-10 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Ear and labyrinth disorders/ Otorrhoea/ RIGHT EAR, BLOODY DRAINAGE	2020-11-10 (26)/ 2020-11-17 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662114; Age (years): 50; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-10-13 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662119; Age (years): 32; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Facial pain/ FACE PAIN	2020-09-27 (10)/ 2020-09-27 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662120; Age (years): 28; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY STATE, UNSPECIFIED	2020-10-14 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Major depression/ MAJOR DEPRESSIVE DISORDER RECUR EPIS-PSYCHOTIC	2020-10-14 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662124; Age (years): 37; Sex: M; Race: OTHER: (b) (6)							
Surgical and medical procedures/ Endodontic procedure/ PERFORATION OF ROOT CANAL SPACE DUE TO ENDODONTIC TREATMENT	2020-11-12 (24)/ 2020-11-12 (24)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662132; Age (years): 42; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA, UNSPECIFIED	2020-09-26 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Tonsillolith/ TONSILLOLITH	2020-10-14 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662143; Age (years): 51; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Dizziness/ MILD DIZZINESS	2020-10-28 09:26 (1)/ 2020-10-28 09:37 (1)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662152; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Malaise/ MALAISE	2020-10-11 (10)/ 2020-10-20 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ UPPER BODY ACHES, A FEW EPISODES	2020-10-11 (10)/ 2020-10-20 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662152; Age (years): 62; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-11 (10)/ 2020-10-20 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-11 (10)/ 2020-10-20 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-15 (14)/ 2020-10-16 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662156; Age (years): 49; Sex: F; Race: OTHER: (b) (6)							
Nervous system disorders/ Paraesthesia/ FELT LIKE ELECTRICITY PASSING THROUGH THE BODY	2020-10-06 20:00 (2)/ 2020-10-07 12:00 (2)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3662156; Age (years): 49; Sex: F; Race: OTHER: (b) (6)							
Ear and labyrinth disorders/ Vertigo positional/ BENIGN PAROXYSMAL VERTIGO, UNSPECIFIED EAR	2020-10-24 (20)/ 2020-10-31 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Ear pruritus/ BILATERAL EAR ITCHING	2020-10-29 (25)/ 2020-11-18 (45)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chest discomfort/ CHEST PRESSURE (TIGHTNESS)	2020-11-11 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662156; Age (years): 49; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN FOLLOWING SPINE (THROUGH ENTIRE BACK FROM SHOULDERS TO BUTTOCK)	2020-11-11 (10)/ 2020-11-18 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ BILATERAL PLEURAL PAIN	2020-11-11 (10)/ 2020-11-18 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT TENDERNESS	2020-11-12 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3662156; Age (years): 49; Sex: F; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Pharyngeal erythema/ ERYTYHEMA PHARYNX DIFFUSE	2020-11-17 (16)/ Ongoing	Yes/ Yes/ No	1	No	NA/ NA	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-18 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Dysuria/ PAIN WHEN URINATING	2020-11-18 (17)/ 2020-11-20 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Renal and urinary disorders/ Micturition urgency/ URINARY URGENCY WITHOUT ADDITIONAL URINE FLOW	2020-11-18 (17)/ 2020-11-21 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662172; Age (years): 48; Sex: F; Race: WHITE							
Endocrine disorders/ Goitre/ THYROID GLAND ENLARGEMENT, RIGHT SIDE	2020-11-16 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662175; Age (years): 49; Sex: M; Race: OTHER: (b) (6)							
Ear and labyrinth disorders/ Ear pain/ BILATERAL EAR PAIN	2020-10-26 (7)/ 2020-11-03 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662180; Age (years): 64; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Pruritus/ DISSEMINATED MILD BODY ITCHING	2020-10-22 11:29 (1)/ 2020-10-23 23:59 (2)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Upper-airway cough syndrome/ POST NASAL DRIP	2020-11-08 (18)/ 2020-11-12 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662180; Age (years): 64; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATING	2020-11-09 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chest discomfort/ MILD CHEST TIGHTNESS	2020-11-09 (19)/ 2020-11-14 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Ear canal erythema/ BILATERAL ERYTHEMA OF CANALS	2020-11-10 (20)/ 2020-11-18 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662180; Age (years): 64; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Ear and labyrinth disorders/ Tympanic membrane hyperaemia/ BILATERAL ERYTHEMA OF TYMPANIC MEMBRANE	2020-11-10 (20)/ 2020-11-18 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Pruritus/ DISSEMINATED MILD BODY ITCHING	2020-11-18 13:35 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662181; Age (years): 61; Sex: M; Race: MULTIPLE: (b) (6)							
Psychiatric disorders/ Psychotic disorder/ PSYCHOSIS, UNSPECIFIED	2020-10-26 (5)/ 2020-10-30 (9)	Yes/ Yes/ No	3	Yes/3 (2020-10-26/ 2020-10-30)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672006; Age (years): 74; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABSCESS IN 1ST MAXILLARY MOLAR	2020-08-31 (26)/ 2020-09-01 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Oral cavity fistula/ PALATAL FISTULA	2020-09-11 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-10-24 (47)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672023; Age (years): 42; Sex: M; Race: WHITE							
Infections and infestations/ Respiratory tract infection viral/ RESPIRATORY VIRAL INFECTION	2020-10-24 (46)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3672038; Age (years): 47; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS ON LEFT AND RIGHT FOREARMS AND RIGHT BICEP	2020-08-17 (8)/ 2020-09-03 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672054; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection/ RESPIRATORY INFECTION	2020-09-27 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672061; Age (years): 36; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-08 (61)/ 2020-11-15 (68)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672076; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ TORN LEFT ROTATOR CUFF	2020-09-28 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3672081; Age (years): 35; Sex: F; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ADHD	2020-08-17 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-30 (21)/ 2020-10-07 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672097; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-07 (26)/ 2020-10-13 (62)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672108; Age (years): 25; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection/ RESPIRATORY TRACT INFECTION	2020-10-04 (24)/ 2020-10-17 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672121; Age (years): 33; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Endometriosis/ ENDOMETRIOSIS	2020-09-02 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672146; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection viral/ RESPIRATORY VIRAL INFECTION	2020-09-25 (11)/ 2020-10-09 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672150; Age (years): 24; Sex: M; Race: WHITE							
Infections and infestations/ Localised infection/ RIGHT FINGER INFECTION (FUNGAL)	2020-09-19 (5)/ 2020-09-22 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672151; Age (years): 25; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH LOWER EXTREMITIES	2020-08-18 12:15 (1)/ 2020-08-26 (10)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672199; Age (years): 71; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Post procedural haematoma/ HEMATOMA R GROIN FOLLOWING ANGIOPLASTY	2020-10-06 (19)/ 2020-10-08 (21)	Yes/ Yes/ No	3	Yes/3 (2020-10-06/ 2020-10-08)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672215; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media/ RIGHT OTITIS MEDIA	2020-09-01 (13)/ 2020-09-09 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672230; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-17 (31)/ 2020-11-02 (47)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672231; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACK INFECTION	2020-08-31 (12)/ 2020-09-11 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672232; Age (years): 68; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-09-10 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3672243; Age (years): 46; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Corneal abrasion/ LEFT CORNEAL ABRASION	2020-09-01 (12)/ 2020-09-07 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672244; Age (years): 47; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-11 (55)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672260; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection/ RESPIRATORY TRACT INFECTION	2020-10-05 (14)/ 2020-10-12 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672273; Age (years): 66; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma of skin/ SQUAMOUS CELL SKIN CANCER (LEFT CHEEK)	2020-09-18 (26)/ 2020-10-06 (44)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3672278; Age (years): 78; Sex: M; Race: WHITE							
Nervous system disorders/ Speech disorder/ SPEECH DEFICIT	2020-09-10 (11)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-09-10/ 2020-09-11)/4	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672278; Age (years): 78; Sex: M; Race: WHITE							
Nervous system disorders/ Ischaemic stroke/ ISCHEMIC STROKE (FRONTAL LOBE)	2020-09-10 (11)/ 2020-09-11 (12)	Yes/ Yes/ No	4	Yes/3 (2020-09-10/ 2020-09-11)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: AE OF SPEECH DEFICIT
Subject ID: US3672279; Age (years): 71; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ DEEPLY BRUISED LEFT KNEE	2020-09-03 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3672290; Age (years): 28; Sex: M; Race: WHITE							
Infections and infestations/ Respiratory tract infection viral/ RESPIRATORY VIRAL INFECTION	2020-10-19 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672300; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection/ RESPIRATORY TRACT INFECTION	2020-09-15 (22)/ 2020-09-26 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Tooth infection/ INFECTION OF MOLAR ON TOP LEFT SIRE OF MOUTH	2020-10-13 (12)/ 2020-10-27 (26)	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural pain/ PAIN SECONDARY TO ROOT CANAL PROCEDURE	2020-10-27 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672332; Age (years): 29; Sex: M; Race: WHITE							
Infections and infestations/ Respiratory tract infection viral/ RESPIRATORY VIRAL INFECTION	2020-10-22 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3672367; Age (years): 21; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN/ CONSTIPATION	2020-11-14 (52)/ 2020-11-14 (52)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672372; Age (years): 24; Sex: F; Race: ASIAN							
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-10-19 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672374; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection viral/ RESPIRATORY VIRAL INFECTION	2020-10-29 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3672380; Age (years): 32; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ INDEX FINGER (LEFT) LACERATION	2020-10-01 (7)/ 2020-10-16 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672407; Age (years): 41; Sex: F; Race: WHITE							
Cardiac disorders/ Arrhythmia/ ARRHYTHMIA	2020-09-07 (5)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3682012; Age (years): 66; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682034; Age (years): 64; Sex: M; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-09-30 (3)/ 2020-09-30 (3)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3682035; Age (years): 63; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-14 (17)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3682062; Age (years): 40; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-12 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682082; Age (years): 67; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ DECAYED TOOTH	2020-10-20 (13)/ 2020-10-20 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3682139; Age (years): 33; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-30 (14)/ 2020-10-01 (15)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Asthenia/ WEAKNESS	2020-09-30 (14)/ 2020-10-04 (18)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-09-30 (14)/ 2020-10-04 (18)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682139; Age (years): 33; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-16 09:00 (1)/ 2020-10-29 09:00 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3682142; Age (years): 57; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ LEFT ANKLE SPRAIN	2020-11-09 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3682153; Age (years): 44; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Epididymitis/ LEFT EPIDIDYMITIS	2020-10-13 (23)/ 2020-10-18 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3682171; Age (years): 60; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Helicobacter infection/ H. PYLORI INFECTION	2020-11-18 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682198; Age (years): 46; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ CUT INJURY TO RIGHT WRIST	2020-10-29 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3682208; Age (years): 55; Sex: M; Race: OTHER: (b) (6)							
Metabolism and nutrition disorders/ Dyslipidaemia/ DYSLIPIDEMIA	2020-11-05 (21)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3692013; Age (years): 28; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Eustachian tube dysfunction/ EUSTACHIAN TUBE DYSFUNCTION	2020-09-05 (8)/ 2020-09-09 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692013; Age (years): 28; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-05 (8)/ 2020-09-09 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ NASAL DISCHARGE	2020-09-05 (8)/ 2020-09-09 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692016; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Peripheral artery aneurysm/ ILIAC ARTERY ANEURYSM	2020-11-01 (40)/ 2020-11-02 (41)	Yes/ Yes/ No	2	Yes/3 (2020-11-01/ 2020-11-08)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692046; Age (years): 50; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF BACK PAIN	2020-09-17 (14)/ 2020-09-17 (14)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692065; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-09-27 (23)/ 2020-10-03 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692081; Age (years): 54; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Tinnitus/ WORSENING OF TINNITUS	2020-09-16 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692088; Age (years): 56; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-01 (22)/ 2020-10-09 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692088; Age (years): 56; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-01 (22)/ 2020-10-09 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Paranasal sinus hypersecretion/ SINUS DRAINAGE	2020-10-05 (26)/ 2020-10-09 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692199; Age (years): 35; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-11-02 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Depression/ DEPRESSION	2020-11-02 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702044; Age (years): 47; Sex: F; Race: WHITE							
Immune system disorders/ Drug hypersensitivity/ MACROBID ALLERGIC REACTION	2020-11-09 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-09 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3712013; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-19 (12)/ 2020-10-05 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3712026; Age (years): 67; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	2020-09-16 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3712039; Age (years): 21; Sex: F; Race: WHITE							
Infections and infestations/ Asymptomatic COVID-19/ COVID ASYMPTOMATIC	2020-11-06 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3712052; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ Ear infection/ LEFT EAR INFECTION	2020-11-02 (19)/ 2020-11-09 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3712076; Age (years): 38; Sex: M; Race: ASIAN							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-10-22 (8)/ 2020-11-01 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3712078; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-04 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3712114; Age (years): 70; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-10-01 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3712116; Age (years): 39; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Synovial cyst/ RIGHT WRIST GANGLION CYST	2020-11-05 (18)/ 2020-11-05 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3712131; Age (years): 42; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION TO LEFT KNEE	2020-10-06 (13)/ 2020-10-22 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3712159; Age (years): 35; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19 SYMPTOMATIC	2020-10-20 09:25 (28)/ 2020-11-11 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3712167; Age (years): 38; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LEFT HAND 4TH FINGER LACERATION	2020-10-28 (6)/ 2020-11-03 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3712235; Age (years): 33; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT (RUQ) PAIN	2020-11-02 (12)/ 2020-11-02 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3712248; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Body tinea/ TINEA CORPORIS	2020-11-03 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722034; Age (years): 65; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ MULTILEVEL LUMBAR SPONDYLOSIS	2020-09-01 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Insomnia/ WORSENING OF INSOMNIA	2020-09-01 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Large intestine polyp/ METAPLASTIC POLYPS IN COLON	2020-09-01 (2)/ 2020-09-01 (2)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Investigations/ Blood iron decreased/ LOW IRON	2020-09-04 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3722034; Age (years): 65; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer metastatic/ METASTATIC CASTRATE SENSITIVE PROSTRATE CANCER WITH METASTASES	2020-09-23 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3722064; Age (years): 22; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ HUMAN RHINOVIRUS	2020-09-17 (18)/ 2020-09-22 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722066; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ POSITIVE COVID 19	2020-11-11 (76)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-16/)	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3722133; Age (years): 54; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH BILATERAL UPPER ARMS AND CHEST	2020-10-09 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3722233; Age (years): 54; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-15 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-17 (5)/ 2020-08-17 (5)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722297; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ POSSIBLE COVID 19	2020-10-26 14:00 (40)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3722306; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-01 (14)/ 2020-09-04 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ MILD NASAL CONGESTION	2020-09-01 (14)/ 2020-09-11 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-02 (15)/ 2020-09-11 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3722306; Age (years): 38; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYLAGIA	2020-09-03 (16)/ 2020-09-04 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-03 (16)/ 2020-09-10 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722338; Age (years): 73; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Umbilical hernia/ UMBILICAL HERNIA	2020-10-13 (27)/ 2020-10-21 (35)	Yes/ Yes/ No	3	Yes/3 (2020-10-13/ 2020-10-21)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722375; Age (years): 28; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-02 10:30 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722382; Age (years): 73; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-15 (24)/ 2020-11-02 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722419; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 POSITIVE	2020-10-16 08:00 (32)/ 2020-10-29 17:00 (46)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732001; Age (years): 84; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bursitis/ LEFT HIP BURSITIS	2020-08-10 (8)/ 2020-09-18 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732008; Age (years): 76; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-06 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732015; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ Balanitis candida/ CANDIDA BALANTIS	2020-11-08 (68)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732020; Age (years): 39; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ WORSENING NON-MIGRAINE HEADACHES	2020-09-10 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Viral pharyngitis/ PHARYNGITIS, VIRAL	2020-09-23 (21)/ 2020-10-02 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732031; Age (years): 69; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	2020-09-09 (3)/ 2020-10-24 (48)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732032; Age (years): 45; Sex: M; Race: ASIAN							
Nervous system disorders/ Presyncope/ VASOVAGAL EPISODE	2020-08-10 12:20 (1)/ 2020-08-10 13:15 (1)	Yes/ Yes/ No	2	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	2020-08-14 (5)/ 2020-08-24 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732051; Age (years): 65; Sex: M; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Dry throat/ INTERMITTENT DRY THROAT	2020-08-19 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Viral sinusitis/ SINUSITIS, VIRAL	2020-10-22 (44)/ 2020-11-02 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732056; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-10 (56)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	
Subject ID: US3732058; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-08-13 11:14 (1)/ 2020-08-13 11:18 (1)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ UNCOMPLICATED URINARY TRACT INFECTION	2020-10-28 (49)/ 2020-11-05 (57)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT NON-MIGRAINE HEADACHE	2020-11-04 (56)/ 2020-11-08 (60)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732063; Age (years): 47; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-15 (6)/ 2020-09-22 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732067; Age (years): 69; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ LOW BACK STRAIN	2020-09-19 (9)/ 2020-09-30 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732075; Age (years): 54; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ ADVERSE REACTION TO FLU AND SHINGLES VACCINE-CHILLS	2020-10-16 (37)/ 2020-10-16 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732075; Age (years): 54; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ ADVERSE REACTION TO FLU AND SHINGLES VACCINE-GENERAL BODY ACHES	2020-10-16 (37)/ 2020-10-16 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Vaccination complication/ ADVERSE REACTION TO FLU AND SHINGLES VACCINE-HEADACHE	2020-10-16 (37)/ 2020-10-16 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ ADVERSE REACTION TO FLU AND SHINGLES VACCINE-GENERAL MUSCLE ACHES	2020-10-16 (37)/ 2020-10-16 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732075; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-04 (56)/ 2020-11-14 (66)	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732088; Age (years): 54; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ RHINITIS, ALLERGIC	2020-09-20 (6)/ 2020-09-29 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732089; Age (years): 60; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-09-04 (18)/ 2020-10-07 (51)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732090; Age (years): 78; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-18 15:06 (1)/ 2020-10-05 (49)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732090; Age (years): 78; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Ecchymosis/ LEFT DELTOID ECCHYMOSIS	2020-08-19 (2)/ 2020-09-18 (32)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Hypoaesthesia/ BILATERAL BUTTOCK NUMBNESS	2020-09-29 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Hypoaesthesia/ BILATERAL KNEE NUMBNESS	2020-09-29 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Pelvic mass/ PELVIC CALCIFIED MASS	2020-10-05 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732091; Age (years): 61; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ RIGHT SHOULDER STRAIN	2020-10-06 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3732095; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-04 (19)/ 2020-10-09 (24)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732098; Age (years): 70; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Large intestine polyp/ COLON POLYPS	2020-09-14 (27)/ 2020-09-14 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3732102; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT WRIST SPRAIN	2020-09-16 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732110; Age (years): 81; Sex: M; Race: WHITE							
Product issues/ Lead dislodgement/ DISPLACED AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD	2020-10-08 (22)/ 2020-10-08 (22)	Yes/ Yes/ No	2	Yes/3 (2020-10-08/ 2020-10-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural pain/ POST SURGICAL PAIN BILATERAL SHOULDERS RELATED TO DISPLACE AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD PROCEDURE	2020-10-08 (22)/ 2020-10-29 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732113; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Viral rhinitis/ VIRAL RHINITIS	2020-09-21 (5)/ 2020-09-23 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732118; Age (years): 51; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ RIGHT MOLAR TOOTH ACHE	2020-08-30 (11)/ 2020-10-21 (63)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732120; Age (years): 20; Sex: M; Race: WHITE							
Infections and infestations/ Tonsillitis/ ACUTE TONSILLITIS, VIRAL	2020-08-27 (8)/ 2020-09-04 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-03 (48)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3732124; Age (years): 55; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Nervous system disorders/ Headache/ NON MIGRAINE HEADACHES	2020-09-15 (26)/ 2020-09-15 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732126; Age (years): 59; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ PAIN STATUS POST LEFT ROTATOR CUFF REPAIR	2020-09-23 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732130; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LEG/ THIGH PAIN	2020-08-22 (2)/ 2020-09-18 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732148; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-09-13 (11)/ 2020-09-17 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732153; Age (years): 28; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-09 (17)/ 2020-09-15 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3732153; Age (years): 28; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Viral upper respiratory tract infection/ VIRAL UPPER RESPIRATORY INFECTION	2020-09-20 (28)/ 2020-10-01 (39)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732154; Age (years): 23; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Tonsillitis/ TONSILLITIS	2020-10-11 (20)/ 2020-10-16 (25)	Yes/ Yes/ No	2		NR	APPLICABLE/ CONCOMITANT MEDICATION	RESOLVED
Subject ID: US3732155; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT WRIST PAIN	2020-08-31 (7)/ 2020-08-31 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732156; Age (years): 56; Sex: F; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-05 (70)/ Ongoing	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3732176; Age (years): 85; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ INSECT BITES BILATERAL LOWER AND UPPER EXTREMITIES	2020-08-31 (6)/ 2020-08-31 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS, BILATERAL LOWER EXTREMITIES	2020-08-31 (6)/ 2020-10-23 (59)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-15 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3732185; Age (years): 57; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Respiratory fume inhalation disorder/ COUGH SECONDARY TO SMOKE INHALATION	2020-09-03 (9)/ 2020-11-13 (80)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732191; Age (years): 57; Sex: F; Race: ASIAN							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-01 (40)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732193; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING JOINT ACHES ON LEFT HAND, RING FINGER, AND THUMB	2020-09-07 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3732193; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	2020-10-26 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3732196; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-20 (25)/ 2020-09-28 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732198; Age (years): 65; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-29 (3)/ 2020-09-01 (6)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Herpes zoster/ SHINGLES - LEFT BUTTOCK	2020-08-30 (4)/ 2020-09-24 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732198; Age (years): 65; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Peripheral swelling/ RIGHT HAND SWELLING	2020-09-04 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Erythema/ RIGHT HAND REDNESS - MEDIAL	2020-09-04 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-28 (35)/ 2020-11-01 (39)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732207; Age (years): 30; Sex: M; Race: ASIAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-09-15 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	UNKNOWN

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732210; Age (years): 41; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Dyspepsia/ CHEST PAIN, LIKELY SECONDARY TO INDIGESTION	2020-08-31 (4)/ 2020-08-31 (4)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION	2020-09-07 (11)/ 2020-09-30 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Viral upper respiratory tract infection/ VIRAL UPPER RESPIRATORY INFECTION	2020-09-12 (16)/ 2020-09-27 (31)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732229; Age (years): 52; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL HIP PAIN	2020-10-02 (5)/ 2020-10-02 (5)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732249; Age (years): 80; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-22 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732261; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chest discomfort/ CHEST PRESSURE	2020-10-01 (2)/ 2020-10-08 (9)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732264; Age (years): 47; Sex: F; Race: WHITE							
Infections and infestations/ Viral sinusitis/ SINUSITIS, VIRAL	2020-11-13 (45)/ 2020-11-15 (47)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732276; Age (years): 32; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION - LEFT FINGER	2020-09-25 (22)/ 2020-10-01 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732280; Age (years): 32; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOLS	2020-09-24 (21)/ 2020-09-24 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE, INTERMITTENT	2020-09-26 (23)/ 2020-09-28 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-09-26 (23)/ 2020-10-01 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732280; Age (years): 32; Sex: F; Race: ASIAN							
Eye disorders/ Dry eye/ BILATERAL DRY EYES	2020-10-01 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	
Injury, poisoning and procedural complications/ Arthropod bite/ UPPER RIGHT CHEST BUG BITE	2020-10-04 (31)/ 2020-10-07 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732281; Age (years): 44; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-18 (13)/ 2020-10-19 (14)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-22 (17)/ 2020-10-22 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732285; Age (years): 66; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS	2020-10-02 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-06 (5)/ 2020-10-08 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732298; Age (years): 43; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-30 (22)/ 2020-09-30 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Rhinovirus infection/ HUMAN RHINOVIRUS/ENTEROVIRUS	2020-10-05 (27)/ 2020-10-13 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732304; Age (years): 55; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ BILATERAL PULMONARY EMBOLISM	2020-10-29 (23)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-29/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3732306; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-25 (19)/ 2020-10-31 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732307; Age (years): 29; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ RIGHT FOOT CONTUSION	2020-10-16 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3732337; Age (years): 41; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-26 (12)/ 2020-10-04 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732339; Age (years): 37; Sex: M; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash/ RASHES ALL OVER BODY (EXCEPT FACE AND NECK)	2020-10-06 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732341; Age (years): 55; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER, UNSPECIFIED	2020-10-07 (23)/ 2020-10-07 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732355; Age (years): 38; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-15 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732357; Age (years): 39; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ BILATERAL FOREARM MUSCLE ACHES	2020-11-08 (25)/ 2020-11-11 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732362; Age (years): 37; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-25 (5)/ 2020-09-25 (5)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-26 (6)/ 2020-10-03 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732368; Age (years): 32; Sex: M; Race: ASIAN							
Vascular disorders/ Hypertension/ HYPTERTENSION	2020-09-22 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732371; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Viral upper respiratory tract infection/ VIRAL UPPER RESPIRATORY INFECTION	2020-11-02 (13)/ 2020-11-06 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732376; Age (years): 50; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ ACUTE DIARRHEAL ILLNESS	2020-10-26 (4)/ 2020-11-10 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-05 (14)/ 2020-11-05 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732383; Age (years): 41; Sex: M; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN LYMPH NODE RIGHT JAW	2020-11-15 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732387; Age (years): 63; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ NON-MIGRAINE HEADACHE	2020-10-07 (2)/ 2020-10-15 (10)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-07 (2)/ 2020-10-20 (15)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Varicose vein/ LEFT LEG VARICOSE VEINS	2020-11-09 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3742002; Age (years): 22; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS UNSPECIFIED	2020-08-21 (5)/ 2020-09-07 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742008; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-08 (25)/ 2020-10-15 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742010; Age (years): 50; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Tooth impacted/ WISDOM TEETH IMPACTION	2020-10-15 (31)/ 2020-11-05 (52)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742011; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Herpes simplex/ WORSENING OF HSV-1	2020-09-26 (12)/ 2020-09-27 (13)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-27 (43)/ 2020-11-08 (55)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742038; Age (years): 38; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Axillary mass/ PEA SIZE LUMP RIGHT AXILLA	2020-10-09 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742046; Age (years): 64; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Aortic aneurysm/ THORACIC ANEURYSM	2020-10-12 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742047; Age (years): 27; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ INCREASED DEPRESSION SYMPTOMS	2020-10-20 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742052; Age (years): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-27 (9)/ 2020-10-09 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742058; Age (years): 26; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-12 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ NONE	
Subject ID: US3742083; Age (years): 43; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-10-01 (10)/ 2020-10-02 (11)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742099; Age (years): 25; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ STRESS REACTION 2ND METATARSAL	2020-10-14 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742100; Age (years): 64; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary fibrosis/ PULMONARY FIBROSIS	2020-10-01 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Blood and lymphatic system disorders/ Iron deficiency anaemia/ IRON DEFICIENCY ANEMIA	2020-10-30 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-30 (38)/ 2020-11-12 (51)	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742100; Age (years): 64; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ SHORTNESS OF BREATH WITH EXERTION	2020-10-30 (38)/ 2020-11-12 (51)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742109; Age (years): 31; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Viral infection/ VIRAL ILLNESS UNSPECIFIED	2020-10-17 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	
Subject ID: US3742121; Age (years): 29; Sex: M; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 17:20 (1)/ 2020-09-05 14:51 (9)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Panic attack/ PANIC ATTACK	2020-08-28 18:00 (2)/ 2020-08-29 04:00 (2)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742123; Age (years): 36; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-20 (13)/ 2020-11-10 (34)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742124; Age (years): 50; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-09-09 (10)/ 2020-09-14 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742140; Age (years): 65; Sex: F; Race: ASIAN							
Infections and infestations/ Gastroenteritis/ ACUTE GASTROENTERITIS	2020-09-09 (13)/ 2020-09-11 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal discomfort/ STRESS RELATED GI UPSET	2020-09-30 (6)/ 2020-10-08 (14)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742144; Age (years): 32; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN LEFT OCCIPITAL LYMPH NODE	2020-10-21 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3742155; Age (years): 54; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-11-12 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742227; Age (years): 72; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Ligament sprain/ SPRAINED ANKLE	2020-10-08 (9)/ 2020-10-28 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742253; Age (years): 44; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-20 (17)/ 2020-09-29 (26)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742267; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-18 (47)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3742310; Age (years): 43; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-10-05 (26)/ 2020-10-30 (51)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742318; Age (years): 43; Sex: F; Race: NOT REPORTED							
Injury, poisoning and procedural complications/ Thermal burn/ BURN TO RIGHT HAND	2020-09-20 (11)/ 2020-10-04 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742341; Age (years): 50; Sex: M; Race: NOT REPORTED							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT PAIN	2020-09-12 05:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742341; Age (years): 50; Sex: M; Race: NOT REPORTED							
Nervous system disorders/ Paraesthesia/ PARASHESIAS RIGHT LEG	2020-09-12 05:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE DELAYED/ NONE	RECOVERING/ RESOLVING
Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS GENERALIZED	2020-09-12 05:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH	2020-09-12 05:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742342; Age (years): 18; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Major depression/ MAJOR DEPRESSIVE DISORDER WITHOUT PSYCHOTIC FEATURES	2020-09-16 (6)/ 2020-09-17 (7)	Yes/ Yes/ No	3	Yes/3 (2020-09-16/ 2020-09-17)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742363; Age (years): 63; Sex: F; Race: WHITE							
Immune system disorders/ Serum sickness/ SERUM SICKNESS	2020-09-22 (6)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Infections and infestations/ Onychomycosis/ FUNGAL TOE NAIL INFECTION	2020-10-11 (25)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3742364; Age (years): 64; Sex: M; Race: NOT REPORTED							
General disorders and administration site conditions/ Peripheral swelling/ LEG SWELLING	2020-10-01 (15)/ 2020-10-05 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEG PAIN	2020-10-01 (15)/ 2020-10-05 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3742364; Age (years): 64; Sex: M; Race: NOT REPORTED							
Infections and infestations/ Viral infection/ VIRAL ILLNESS UNSPECIFIED	2020-11-06 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742373; Age (years): 70; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION RIGHT MIDDLE FINGER	2020-10-01 (17)/ 2020-10-17 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-11-11 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742380; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME [UNSPECIFIED]	2020-09-23 (9)/ 2020-09-24 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742380; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-13 (29)/ 2020-10-17 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742384; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-11-01 (20)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-01/ 2020-11-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742388; Age (years): 68; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Lichenoid keratosis/ EXACERBATION BENIGN LICHENOID KERATOSIS LEFT FOREARM	2020-09-30 (15)/ 2020-10-25 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Sialoadenitis/ SALIVARY GLAND INFECTION	2020-10-24 (11)/ 2020-10-27 (14)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742395; Age (years): 61; Sex: M; Race: OTHER: (b) (6)							
Vascular disorders/ Deep vein thrombosis/ DEEP VEIN THROMBOSIS	2020-09-25 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742420; Age (years): 21; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-23 (5)/ 2020-10-28 (10)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742423; Age (years): 49; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-11-15 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742442; Age (years): 26; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ GENERALIZED BODY ACHES FROM EXERCISE	2020-10-05 (15)/ 2020-10-12 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742456; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Asthma/ EXACERBATED ASTHMA	2020-09-29 (8)/ 2020-10-08 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742477; Age (years): 49; Sex: F; Race: NOT REPORTED							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-14 (14)/ 2020-10-31 (31)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752003; Age (years): 51; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Superficial injury of eye/ SCRATCHED EYEBALL	2020-08-08 00:00 (1)/ 2020-08-12 00:00 (5)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752014; Age (years): 25; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-24 (18)/ 2020-08-27 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752014; Age (years): 25; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-24 (18)/ 2020-08-27 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-24 (18)/ 2020-08-27 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-26 (20)/ 2020-08-26 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3752025; Age (years): 58; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest discomfort/ NON-CARDIAC CHEST TIGHTNESS	2020-10-02 (12)/ 2020-10-09 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-02 (12)/ 2020-10-11 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-11-08 (49)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-10/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Hypotension/ HYPOTENSION REQUIRING HOSPITALIZATION	2020-11-10 (51)/ 2020-11-13 (54)	Yes/ Yes/ No	4	Yes/3 (2020-11-10/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3752030; Age (years): 44; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Ear pain/ OTALGIA , RIGHT	2020-09-25 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-25 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752039; Age (years): 37; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ UNSPECIFIED CONTACT DERMATITIS DUE TO PLANT [POISON IVY]	2020-08-25 (15)/ 2020-09-15 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-11 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3752039; Age (years): 37; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-28 (19)/ 2020-09-29 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-29 (20)/ 2020-10-03 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-29 (20)/ 2020-10-03 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3752039; Age (years): 37; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (LOCATION UNKNOWN)	2020-10-02 (23)/ 2020-10-02 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Cardiac disorders/ Palpitations/ PALPITATIONS	2020-10-12 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3752055; Age (years): 41; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Back injury/ BACK INJURY	2020-10-09 (31)/ 2020-10-09 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752065; Age (years): 46; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ INFECTIOUS RHINORRHEA	2020-10-26 (49)/ 2020-10-27 (50)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3752065; Age (years): 46; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sneezing/ SNEEZING	2020-10-26 (49)/ 2020-10-27 (50)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-26 (49)/ 2020-10-28 (51)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-26 (49)/ 2020-10-28 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-26 (49)/ 2020-10-28 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752065; Age (years): 46; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-26 (49)/ 2020-10-29 (52)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752069; Age (years): 31; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-31 (52)/ 2020-11-10 (62)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752085; Age (years): 68; Sex: F; Race: WHITE							
Eye disorders/ Macular hole/ MACULAR HOLE RIGHT EYE	2020-09-03 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3752090; Age (years): 60; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Anaemia/ WORSENING ANEMIA	2020-09-28 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752096; Age (years): 68; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT HIP PAIN	2020-08-31 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-08-31 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Fall/ FALL	2020-08-31 (18)/ 2020-08-31 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752096; Age (years): 68; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS (UNKNOWN LOCATION)	2020-09-22 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer stage IV/ STAGE 4 PROSTATE CANCER	2020-10-16 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to bone/ MULTIFOCAL OSTEOBLASTIC METASTATIC DISEASE	2020-10-28 (42)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752111; Age (years): 40; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Femoroacetabular impingement/ IMPINGEMENT OF THE ACETABULUM	2020-09-25 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3752158; Age (years): 60; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Diabetes mellitus/ WORSENING DIABETES MELLITUS	/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3752161; Age (years): 70; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Lumbar vertebral fracture/ CLOSED FRACTURE OF 2ND AND 3RD LUMBAR	2020-09-16 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752161; Age (years): 70; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT	2020-09-16 (1)/ 2020-09-16 (1)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-09-16 (1)/ 2020-09-16 (1)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19 INFECTION	2020-10-21 (36)/ 2020-11-03 (49)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752162; Age (years): 70; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ FRACTURED FOOT(RIGHT)	2020-09-16 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752162; Age (years): 70; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT	2020-09-16 (1)/ 2020-09-16 (1)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Pulmonary contusion/ CONTUSED RIGHT LUNG(FROM MVA)	2020-09-16 00:00 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Back pain/ L5 S1 DISCECTOMY WITH RIGHT LATERAL HEMILAMINECTOMY DUE TO LOW BACK PAIN	2020-10-15 (30)/ 2020-10-15 (30)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752162; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-17 (32)/ 2020-11-02 (48)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752169; Age (years): 72; Sex: F; Race: WHITE							
Eye disorders/ Ocular rosacea/ OCULAR ROSACEA WORSENING	2020-10-02 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752180; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-12 (24)/ 2020-09-15 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Rhinitis/ INFECTIVE RHINORRHEA	2020-09-12 (24)/ 2020-09-21 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752180; Age (years): 57; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-12 (24)/ 2020-09-21 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-12 (24)/ 2020-09-21 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Tooth abscess/ ABSCESSED TOOTH	2020-10-06 (15)/ 2020-10-14 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752191; Age (years): 60; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Patella fracture/ BROKEN RIGHT PATELLA	2020-09-03 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752193; Age (years): 30; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ LEFT WRIST SPRAIN	2020-08-21 00:00 (1)/ Ongoing	No/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752196; Age (years): 48; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tendon rupture/ RIGHT ACHILLES TENDON TEAR	2020-09-28 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Exostosis/ RIGHT HEEL SPUR	2020-09-28 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3752222; Age (years): 53; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-10-01 (11)/ 2020-10-11 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752229; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-23 (33)/ 2020-11-12 (53)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752250; Age (years): 40; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ POST INJECTION SITE REDNESS OF LEFT ARM NONURTICARIAL	2020-08-30 (6)/ 2020-09-02 (9)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Lip swelling/ LIP SWELLING	2020-09-12 (19)/ 2020-09-19 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-11-08 (48)/ 2020-11-23 (63)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752251; Age (years): 47; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-02 (9)/ 2020-10-07 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (9)/ 2020-10-07 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-02 (9)/ 2020-10-07 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752252; Age (years): 78; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-22 (1)/ 2020-10-05 (14)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752252; Age (years): 78; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-26 (5)/ 2020-09-28 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-26 (5)/ 2020-10-02 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752273; Age (years): 49; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-20 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3752322; Age (years): 47; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin lesion/ STAPH LESION ON THE BACK OF HEAD	2020-09-09 (10)/ 2020-09-14 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752322; Age (years): 47; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Non-cardiac chest pain/ CHEST WALL PAIN(NON-CARDIAC)	2020-10-01 (3)/ 2020-10-12 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-01 (3)/ 2020-10-12 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752324; Age (years): 69; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Sciatica/ RIGHT HIP SCIATIC NERVE PAIN	2020-09-15 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752335; Age (years): 49; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ RIGHT INDEX FINGER LACERATION	2020-09-20 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3752344; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-11 (11)/ 2020-10-23 (23)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752346; Age (years): 39; Sex: F; Race: WHITE							
Investigations/ Glycosylated haemoglobin increased/ PREDIABETIC: ELEVATED A1C LEVEL	2020-10-19 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3752347; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-09 (12)/ 2020-10-16 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752353; Age (years): 40; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-12 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-09-12 (11)/ 2020-09-19 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-15 (14)/ 2020-09-18 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-15 (14)/ 2020-09-19 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752353; Age (years): 40; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-15 (14)/ 2020-09-19 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752362; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-09-06 (5)/ 2020-09-20 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752366; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-04 (3)/ 2020-09-16 (15)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752398; Age (years): 67; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-10-08 (7)/ 2020-10-08 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752398; Age (years): 67; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-10-22 (21)/ 2020-10-22 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752419; Age (years): 67; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-15 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3762018; Age (years): 69; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial tachycardia/ ATRIAL TACHYCARDIA	2020-11-08 (52)/ 2020-11-09 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-11-08 (52)/ 2020-11-09 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762105; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-09-03 (4)/ 2020-09-07 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-09-11 (12)/ 2020-09-18 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3762126; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-07 (40)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3762215; Age (years): 83; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Constipation/ CONSTIPATION	2020-10-30 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3762251; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ Skin infection/ SKIN INFECTION (NOT AT INJECTION SITE)	2020-09-15 (5)/ 2020-09-24 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772004; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-09 (71)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3772007; Age (years): 33; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ DENTAL ABSCESS	2020-09-24 (17)/ 2020-09-30 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772014; Age (years): 77; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-09-19 (12)/ 2020-09-30 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772032; Age (years): 57; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tibia fracture/ FRACTURED TIBIA	2020-08-29 (20)/ 2020-09-03 (25)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772035; Age (years): 32; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-13 (61)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3772036; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS RIGHT EYE LID	2020-11-05 (53)/ 2020-11-11 (59)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772043; Age (years): 38; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain lower/ LOWER ABDOMINAL PAIN	2020-09-30 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772043; Age (years): 38; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Ovarian cyst ruptured/ RUPTURED OVARIAN CYST	2020-09-30 (17)/ 2020-09-30 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: LOWER ABDOMINAL PAIN
Subject ID: US3772051; Age (years): 67; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Incarcerated hernia/ ACUTE INCARCERATED VENTRAL HERNIA	2020-09-04 (24)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-05/ 2020-09-14)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-09-05 (25)/ 2020-09-14 (34)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3772123; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTION OF THE LEFT BIG TOE	2020-09-27 (11)/ 2020-10-09 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772132; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-13 (57)/ 2020-11-16 (60)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772153; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREPTOCOCCAL PHARYNGITIS	2020-11-05 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Vulvovaginal mycotic infection/ YEAST INFECTION VAGINAL	2020-11-11 (28)/ 2020-11-20 (37)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772169; Age (years): 38; Sex: F; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ RENAL STONES	2020-09-16 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772169; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Breast cellulitis/ CELLULITIS ON LEFT BREAST	2020-09-21 (25)/ 2020-09-29 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772177; Age (years): 67; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Iron deficiency/ IRON DEFICIENCY	2020-09-23 (27)/ 2020-11-18 (83)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: CONTINUOUS TREATMENT FOR THIS CONDITION RESOLVED THIS AE.
Subject ID: US3772182; Age (years): 51; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-13 (45)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772198; Age (years): 50; Sex: M; Race: WHITE							
Infections and infestations/ Otitis media/ OTITIS MEDIA	2020-10-20 (23)/ 2020-10-23 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772230; Age (years): 26; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE ON RIGHT HAND	2020-09-14 (10)/ 2020-09-14 (10)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Cellulitis/ CELLULITIS ON HEAD	2020-10-18 (11)/ 2020-10-27 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772235; Age (years): 45; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA EXACERBATION	2020-11-02 (25)/ 2020-11-06 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772239; Age (years): 29; Sex: M; Race: WHITE							
Nervous system disorders/ Migraine/ MIGRAINE	2020-10-06 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3772246; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-11-11 (34)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3772285; Age (years): 80; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-09 (29)/ 2020-11-18 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-11-17 (37)/ 2020-11-20 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782016; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-09 (29)/ 2020-11-09 (60)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782033; Age (years): 35; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-29 (46)/ 2020-11-14 (62)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782050; Age (years): 30; Sex: M; Race: MULTIPLE:				(b) (6)			
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-18 (33)/ 2020-11-06 (52)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782062; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-11-12 (57)/ 2020-11-23 (68)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782063; Age (years): 68; Sex: F; Race: WHITE							
Eye disorders/ Blepharitis/ BILATERAL BLEPHARITIS	2020-09-03 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3782073; Age (years): 56; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Angioedema/ ANGIODEMA	2020-08-28 (5)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3782082; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-31 (40)/ 2020-11-23 (63)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782095; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT FOREARM PAIN	2020-10-10 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782127; Age (years): 41; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTH PAIN	2020-10-06 (8)/ 2020-11-03 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3782136; Age (years): 45; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-07 (39)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3782166; Age (years): 57; Sex: M; Race: WHITE							
Vascular disorders/ Deep vein thrombosis/ LEFT LEG DVT	2020-09-19 (11)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3782168; Age (years): 43; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ PAIN POST CARTILAGE IMPLANT SURGERY	2020-09-17 (7)/ 2020-09-17 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782168; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-06 (26)/ 2020-10-10 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Post procedural infection/ POST-OP INFECTION R TOE	2020-10-21 (9)/ 2020-10-29 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782168; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-10 (29)/ 2020-11-24 (43)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SEE AE #5 AND #6. PARTICIPANT HAS POSSIBLE PERIPHERAL NEUROPATHY AND A RED, MILD, NON-PRURITIC, FLAKY, MALAR RASH.
Nervous system disorders/ Neuropathy peripheral/ POSSIBLE PERIPHERAL NEUROPATHY	2020-11-18 (37)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3782168; Age (years): 43; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash pruritic/ RED, MILDLY PRURITIC, FLAKY, NON-URTICARIAL MALAR RASH	2020-11-18 (37)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3792033; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-09 (16)/ 2020-10-04 (41)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3792079; Age (years): 48; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-29 13:37 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3792089; Age (years): 39; Sex: M; Race: WHITE							
Immune system disorders/ Food allergy/ ALLERGIC REACTION TO FOOD	2020-10-17 (12)/ 2020-10-19 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3792094; Age (years): 66; Sex: M; Race: WHITE							
Investigations/ Blood glucose increased/ ELEVATED BLOOD GLUCOSE	2020-10-20 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Renal and urinary disorders/ Renal cyst/ RIGHT KIDNEY CYST	2020-10-20 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pulmonary congestion/ PULMONARY CONGESTION	2020-10-20 (12)/ 2020-10-22 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3802012; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-11-02 (48)/ Ongoing	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802023; Age (years): 71; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chest pain/ INTERMITTENT CHEST PAIN (UNKNOWN ETIOLOGY)	2020-08-26 (3)/ 2020-08-27 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802024; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus polyp/ SINUS POLYP	2020-09-08 (16)/ 2020-09-08 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802034; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-05 (46)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3802046; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-13 (52)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-21/ 2020-11-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802051; Age (years): 65; Sex: F; Race: WHITE							
Immune system disorders/ Allergy to metals/ ALLERGY TO NICKEL	/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3802083; Age (years): 71; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ RIGHT FOOT INJURY	2020-09-05 (6)/ 2020-09-09 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3802098; Age (years): 32; Sex: M; Race: WHITE							
Cardiac disorders/ Palpitations/ HEART PALPITATIONS	2020-09-22 (22)/ 2020-09-27 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3802109; Age (years): 22; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-12 (11)/ 2020-11-15 (45)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802109; Age (years): 22; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-12 (11)/ 2020-11-15 (45)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Fibromyalgia/ FIBROMYALGIA	2020-10-12 (11)/ 2020-11-15 (45)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Ear infection/ EAR INFECTION	2020-11-12 (42)/ 2020-11-22 (52)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-11-12 (42)/ 2020-11-22 (52)	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802127; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN IN HANDS	2020-10-10 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3802175; Age (years): 22; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Middle ear effusion/ FLUID IN EAR DRUM	2020-09-14 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3802185; Age (years): 52; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-11-11 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3802215; Age (years): 58; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADANOPATHY LEFT AXILLARY, IPSILATERAL	2020-09-27 (17)/ 2020-10-02 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802233; Age (years): 41; Sex: F; Race: WHITE							
Immune system disorders/ Hypersensitivity/ UNSPECIFIED ALLERGIC REACTION, MILD, AND WITHOUT SIGNIFICANT SOFT TISSUE SWELLING OR AIRWAY COMPROMISE - SWOLLEN EARS, TINGLING TONGUE AND LIPS	2020-10-15 (4)/ 2020-10-28 (17)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3802251; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-11-07 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3812002; Age (years): 64; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-10 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812002; Age (years): 64; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-14 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812005; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-10-15 (45)/ 2020-10-20 (50)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812015; Age (years): 41; Sex: M; Race: WHITE							
Immune system disorders/ Hypersensitivity/ WORSENING ALLERGIES	2020-10-05 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812020; Age (years): 34; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Irritable bowel syndrome/ WORSENING IRRITABLE BOWEL SYNDROME	2020-08-04 15:45 (1)/ 2020-09-01 10:00 (29)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812041; Age (years): 22; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER (100.8)	2020-10-11 (42)/ 2020-10-12 (43)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-11 (42)/ 2020-10-14 (45)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-11 (42)/ 2020-10-14 (45)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-11 (42)/ 2020-10-14 (45)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812041; Age (years): 22; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-11 (42)/ 2020-10-14 (45)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812044; Age (years): 60; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ TICK BITES	2020-08-23 (19)/ 2020-10-07 (64)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIA ON BACK AND BLE (DUE TO TICK BITES)	2020-08-23 (19)/ 2020-10-07 (64)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID -19	2020-09-26 (27)/ 2020-10-21 (52)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812059; Age (years): 20; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety disorder/ ANXIETY DISORDER	2020-10-24 (54)/ 2020-11-10 (71)	Yes/ Yes/ No	4	Yes/3 (2020-10-26/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Nicotine dependence/ WORSENING NICOTINE ADDICTION	2020-10-27 (57)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Dissociative disorder/ DISSOCIATIVE DISORDER	2020-10-29 (59)/ 2020-11-10 (71)	Yes/ Yes/ No	4	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Major depression/ SEVERE EPISODE OF RECURRENT MAJOR DEPRESSIVE DISORDER	2020-10-29 (59)/ 2020-11-10 (71)	Yes/ Yes/ No	4	Yes/3 (2020-10-29/ 2020-11-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3812059; Age (years): 20; Sex: F; Race: WHITE							
Psychiatric disorders/ Major depression/ SEVERE EPISODE OF RECURRENT MAJOR DEPRESSIVE DISORDER	2020-11-18 (79)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-18/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812067; Age (years): 33; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-09-14 (11)/ 2020-10-08 (35)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812087; Age (years): 53; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA-WIDESPREAD	2020-09-15 (12)/ 2020-09-18 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-15 (12)/ 2020-09-20 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3812087; Age (years): 53; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-15 (12)/ 2020-09-20 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-17 (14)/ 2020-09-18 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812100; Age (years): 47; Sex: F; Race: WHITE							
Renal and urinary disorders/ Haematuria/ WORSENING HEMATERIA	2020-10-29 (56)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812101; Age (years): 31; Sex: F; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-03 (26)/ 2020-10-03 (26)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3812106; Age (years): 69; Sex: F; Race: WHITE							
Eye disorders/ Conjunctival haemorrhage/ SUBCONJUNCTIVAL HEMORRHAGE RIGHT EYE	2020-09-30 (23)/ 2020-10-03 (26)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Eye disorders/ Conjunctivochalasis/ CONJUNCTIVOCHALASIS	2020-09-30 (23)/ 2020-10-03 (26)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT HIP PAIN	2020-10-31 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3812117; Age (years): 67; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-21 (42)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3812120; Age (years): 76; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Ecchymosis/ ECCHYMOSIS LEFT CHEST	2020-08-25 (15)/ 2020-09-28 (49)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812124; Age (years): 45; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-14 (35)/ 2020-09-17 (38)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812133; Age (years): 33; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-31 (21)/ 2020-09-01 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-31 (21)/ 2020-09-12 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3812143; Age (years): 68; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2020-09-29 (15)/ 2020-10-20 (36)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812154; Age (years): 39; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Ear pain/ LEFT EAR PAIN	2020-09-20 (11)/ 2020-10-01 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN-MUSCULOSKELETAL	2020-10-07 (28)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812154; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-07 (28)/ 2020-10-17 (38)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812164; Age (years): 68; Sex: M; Race: WHITE							
Renal and urinary disorders/ Pollakiuria/ FREQUENT URINATION	2020-10-07 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812168; Age (years): 38; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19 INFECTION	2020-11-05 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812169; Age (years): 67; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-27 (14)/ 2020-09-03 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812174; Age (years): 18; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-08-14 (1)/ 2020-09-26 (44)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812175; Age (years): 25; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-10-29 (50)/ 2020-11-03 (55)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-29 (50)/ 2020-11-03 (55)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-11 (63)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812175; Age (years): 25; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-17 (69)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812183; Age (years): 70; Sex: M; Race: WHITE							
Renal and urinary disorders/ Micturition urgency/ WORSENING URINARY URGENCY	2020-08-20 (6)/ 2020-10-02 (49)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812197; Age (years): 38; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-24 (8)/ 2020-09-26 (41)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812199; Age (years): 75; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP PAIN	2020-10-07 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812199; Age (years): 75; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING LEFT HIP PAIN	2020-10-07 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812204; Age (years): 72; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-30 (13)/ 2020-10-16 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ WORSENING CHRONIC COUGH	2020-09-30 (13)/ 2020-10-19 (32)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812209; Age (years): 47; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ RIGHT KNEE WORSENING OSTEOARTHRITIS	2020-10-06 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3812216; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-11 (25)/ 2020-11-10 (55)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Dental caries/ LEFT TOOTH CAVITY	2020-11-06 (51)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812217; Age (years): 64; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING PAIN LEFT MENISCUS	2020-09-28 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3812228; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Trichomoniasis/ TRICHOMONIASIS	2020-11-02 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Gonorrhoea/ GONORRHEA	2020-11-02 (46)/ 2020-11-12 (56)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hyperlipidaemia/ WORSENING HYPERLIPIDEMIA	2020-11-05 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812229; Age (years): 81; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foreign body in ear/ FOREIGN BODY IN LEFT EAR	2020-09-07 (18)/ 2020-09-07 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812239; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE	2020-08-24 (4)/ 2020-08-24 (4)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACK INFECTION	2020-10-30 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	2020-10-30 (38)/ 2020-10-30 (38)	Yes/ Yes/ No	4	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812243; Age (years): 44; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Bartholin's cyst/ BARTHOLIN'S CYST	2020-09-14 (25)/ 2020-09-21 (32)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812247; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Skin laceration/ RIGHT HAND LACERATION	2020-10-01 (15)/ 2020-10-30 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812266; Age (years): 34; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ BROKEN TOOTH	2020-09-25 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812266; Age (years): 34; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ CHIPPED WISDOM TOOTH	2020-09-25 (3)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812272; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-13 (51)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812280; Age (years): 29; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-10-05 (12)/ 2020-10-27 (34)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-19 (26)/ 2020-10-25 (32)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812280; Age (years): 29; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-11-12 (50)/ 2020-11-17 (55)	Yes/ Yes/ No	4	Yes/3 (2020-11-13/ 2020-11-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-13 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812287; Age (years): 57; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LEFT HAND LACERATION	2020-09-08 (12)/ 2020-10-08 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812289; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-15 (19)/ 2020-09-15 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812289; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-15 (19)/ 2020-09-16 (20)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-15 (19)/ 2020-09-19 (23)	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIA	2020-09-15 (19)/ 2020-09-19 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-16 (20)/ 2020-09-17 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812289; Age (years): 47; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ INTERMITTENT DIFFICULTY BREATHING	2020-09-16 (20)/ 2020-09-17 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-16 (20)/ 2020-09-19 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-16 (20)/ 2020-09-19 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812305; Age (years): 23; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-20 (20)/ 2020-09-20 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-09-20 (20)/ 2020-09-20 (20)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-20 (20)/ 2020-09-20 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812309; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-16 (14)/ 2020-10-01 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812309; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION (DISCOVERED ON CT SCAN OF SINUSES)	2020-10-15 (16)/ 2020-10-25 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Tinnitus/ BILATERAL TINNITUS	2020-10-18 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812321; Age (years): 68; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Large intestine polyp/ COLON POLYP	2020-11-05 (28)/ 2020-11-05 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812323; Age (years): 28; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19 INFECTION	2020-10-28 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812343; Age (years): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-27 (4)/ 2020-10-05 (12)	Yes/ Yes/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-29 (6)/ 2020-10-08 (15)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812343; Age (years): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ INTERMITTENT COUGH	2020-09-29 (6)/ 2020-10-13 (20)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822006; Age (years): 51; Sex: F; Race: WHITE							
Eye disorders/ Eye swelling/ SWELLING UNDER EYE, BILATERAL	2020-08-09 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822015; Age (years): 83; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiac failure/ HEART FAILURE	2020-09-09 (7)/ 2020-09-12 (10)	Yes/ Yes/ No	2	Yes/3 (2020-09-09/ 2020-09-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: CONTINUING ON OXYGEN
General disorders and administration site conditions/ Oedema peripheral/ BILATERAL EDEMA, LEGS	2020-09-10 (8)/ 2020-09-12 (10)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822019; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Asthma/ WORSENING OF ASTHMA	2020-08-20 (16)/ 2020-08-20 (16)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822038; Age (years): 43; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-07 11:45 (1)/ 2020-08-07 11:59 (1)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Peripheral swelling/ BILATERAL SWELLING IN LOWER EXTREMITIES	2020-10-16 (39)/ 2020-10-17 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822119; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-03 08:00 (21)/ 2020-09-06 (25)	Yes/ Yes/ No	3	Yes/3 (2020-09-04/ 2020-09-06)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822119; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Sepsis/ SEPSIS	2020-09-04 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ NONE	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Mental status changes/ ALTERED MENTAL STATUS DUE TO SEPSIS	2020-09-04 (23)/ 2020-09-06 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822330; Age (years): 56; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ FINGER LACERATION RESULTING IN STICHES	2020-10-04 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3832007; Age (years): 48; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-11-09 (74)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832008; Age (years): 52; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin abrasion/ BILATERAL FOREARM ABRASIONS	2020-08-07 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3832014; Age (years): 56; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-08-31 (4)/ 2020-09-02 (6)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Investigations/ Brain natriuretic peptide increased/ ELEVATED BRAIN NATRIURETIC PEPTIDE LEVEL	2020-08-31 (4)/ 2020-09-02 (6)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832014; Age (years): 56; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	2020-08-31 (4)/ 2020-09-02 (6)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Mental status changes/ ALTERED MENTAL STATUS	2020-08-31 (4)/ 2020-09-02 (6)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertensive emergency/ HYPERTENSIVE EMERGENCY	2020-08-31 (4)/ 2020-09-02 (6)	Yes/ Yes/ No	3	Yes/3 (2020-08-31/ 2020-09-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832019; Age (years): 46; Sex: M; Race: WHITE							
Infections and infestations/ Eye infection bacterial/ BACTERIAL INFECTION IN LEFT EYE	2020-10-22 (56)/ 2020-11-05 (70)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832037; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Staphylococcal skin infection/ STAPH INFECTION - RIGHT FOOT	2020-08-21 (21)/ 2020-08-31 (31)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832047; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-07 (8)/ 2020-09-12 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832062; Age (years): 67; Sex: F; Race: WHITE							
Immune system disorders/ Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2020-09-29 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832074; Age (years): 82; Sex: F; Race: WHITE							
Cardiac disorders/ Acute myocardial infarction/ ST ELEVATION MYOCARDIAL INFARCTION (UNSPECIFIED ARTERY)	2020-09-16 (44)/ 2020-09-18 (46)	Yes/ Yes/ No	3	Yes/3 (2020-09-16/ 2020-09-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3832075; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Abscess limb/ LEFT LEG ABSCESS	2020-08-25 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832081; Age (years): 20; Sex: F; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ WORSENING OF ATTENTION-DEFICIT /HYPERACTIVITY DISORDER	2020-09-24 (24)/ 2020-09-24 (24)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: WORSENING OF CONDITION IS RESOLVED WITH ONGOING INCREASE IN MEDICATION DOSAGE .

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832087; Age (years): 68; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY DERMATITIS	2020-09-18 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832106; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-10-14 (43)/ 2020-10-18 (47)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832109; Age (years): 21; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ POST SURGICAL PAIN	2020-10-15 (43)/ 2020-10-29 (57)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832118; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-22 (20)/ 2020-09-25 (23)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832121; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-22 (50)/ 2020-10-30 (58)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832124; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-21 (18)/ 2020-09-27 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832131; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABSCESSED TOOTH	2020-09-26 (23)/ 2020-11-06 (64)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: FULL MOUTH EXTRACTION COMPLETED AND DENTURES PLACED
Subject ID: US3832134; Age (years): 40; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-05 (2)/ 2020-09-09 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832134; Age (years): 40; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Metabolism and nutrition disorders/ Folate deficiency/ FOLATE DEFICIENCY	2020-09-22 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832139; Age (years): 40; Sex: F; Race: WHITE							
Endocrine disorders/ Hypothyroidism/ HYPOTHYROIDISM	2020-09-28 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3832154; Age (years): 52; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ankle fracture/ FRACTURE OF LEFT LATERAL MALLEOLUS	2020-08-12 17:43 (2)/ 2020-09-30 (51)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832156; Age (years): 66; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-01 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832159; Age (years): 59; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ WORSENING OF GASTROESOPHAGEAL REFLUX DISEASE	2020-10-09 (29)/ 2020-10-09 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT'S WORSENING OF CONDITION HAS RESOLVED WITH ADDITIONAL MEDICATION.
Subject ID: US3832187; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-08-31 (19)/ 2020-09-11 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832198; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Nasopharyngitis/ COMMON COLD	2020-09-21 (36)/ 2020-09-25 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832198; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-26 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832199; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ Acute sinusitis/ ACUTE SINUSITIS	2020-09-01 (16)/ 2020-09-12 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832211; Age (years): 76; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ COPD EXACERBATION	2020-10-08 (24)/ 2020-10-16 (32)	Yes/ Yes/ No	3	Yes/3 (2020-10-08/ 2020-10-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832214; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABSCESSED TOOTH	2020-09-03 (17)/ 2020-09-07 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3832215; Age (years): 71; Sex: M; Race: WHITE							
Endocrine disorders/ Androgen deficiency/ TESTOSTERONE DEFICIENCY	2020-09-29 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832237; Age (years): 50; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-08 (22)/ 2020-10-15 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT REPORTS THAT INCREASED MEDICATION HAS HELPED WITH HYPERTENSION. SUBJECT CONTINUES ON CURRENT DOSE OF LOSARTAN
Subject ID: US3832239; Age (years): 34; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-07 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3832249; Age (years): 79; Sex: M; Race: WHITE							
Cardiac disorders/ Coronary artery disease/ WORSENING OF CORONARY ARTERY DISEASE	2020-10-21 (30)/ 2020-10-21 (30)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT WENT IN FOR A ROUTINE HEART CATHERIZATION SECOND TO HIGH CHOLESTEROL. DURING THE PROCEDURE, A 96% BLOCKAGE WAS IDENTIFIED. CARDIAC STENT PLACED IN BLOCKED ARTERY AND SUBJECT STARTED ON PLAVIX

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Subject ID: US3832252; Age (years): 77; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Lipoma/ LIPOMA ON RIGHT SHOULDER	2020-10-20 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832256; Age (years): 55; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF BACK PAIN	2020-09-14 (20)/ 2020-09-23 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: STARTED NAPROXEN
Subject ID: US3832258; Age (years): 60; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-30 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3842017; Age (years): 40; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Gout/ GOUT FLARE UP (LEFT BIG TOE)	2020-09-08 (5)/ 2020-09-18 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3842028; Age (years): 30; Sex: F; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Acne/ ACNE	2020-11-06 (30)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3842038; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-05 (23)/ 2020-11-12 (30)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Dementia/ MILD SUGGESTIVE DEMENTIA	2020-11-10 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852005; Age (years): 67; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	2020-10-08 (23)/ 2020-10-21 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852014; Age (years): 60; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-09-12 (20)/ 2020-09-19 (27)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852016; Age (years): 69; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Lower limb fracture/ FRACTURED LEG (RIGHT)	2020-09-03 (11)/ 2020-11-10 (79)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT TO COMPLETE PHYSICAL THERAPY TO STRENGTHEN GAIT AND INCREASE ROM

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852035; Age (years): 63; Sex: M; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-10-06 (14)/ 2020-10-23 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852045; Age (years): 56; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-09-04 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Ear infection/ BILATERAL EAR INFECTION	2020-10-10 (17)/ 2020-10-14 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852050; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-08-30 (4)/ 2020-09-06 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852051; Age (years): 72; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ DENTAL PAIN DUE TO SURGICAL PROCEDURE	2020-09-01 (6)/ 2020-09-13 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diverticulum/ DIVERTICULOSIS	2020-11-03 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Hiatus hernia/ HIATAL HERNIA	2020-11-03 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3852054; Age (years): 44; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT FOOT PAIN	2020-10-15 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852070; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-03 (9)/ 2020-10-17 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852090; Age (years): 37; Sex: F; Race: ASIAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-03 (37)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3852096; Age (years): 69; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ SURGICAL PAIN FROM URETHRAL SLING	2020-09-10 (8)/ 2020-09-16 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3852102; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-10-26 (25)/ 2020-10-27 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852102; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Anosmia/ LOSS OF SMELL	2020-10-26 (25)/ 2020-10-27 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852124; Age (years): 36; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-26 (4)/ 2020-10-30 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852134; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-26 (19)/ 2020-10-31 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852140; Age (years): 73; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CA RIGHT CHEST	2020-10-12 (8)/ 2020-10-12 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852147; Age (years): 73; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-07 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3852176; Age (years): 31; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-29 (21)/ 2020-10-31 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852178; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-07 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3862005; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-10 (2)/ 2020-09-18 (10)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862005; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoporosis/ OSTEOPOROSIS	2020-11-05 (58)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862015; Age (years): 68; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-10-05 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3862020; Age (years): 61; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2020-10-30 (45)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862026; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-06 (20)/ 2020-09-21 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862044; Age (years): 52; Sex: M; Race: WHITE							
Investigations/ Heart rate irregular/ IRREGULAR HEART BEAT	2020-09-10 (21)/ 2020-09-10 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3862050; Age (years): 50; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-29 (6)/ 2020-09-11 (19)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862053; Age (years): 74; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-10-16 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-23 12:45 (32)/ 2020-10-31 (41)	Yes/ Yes/ No	3	Yes/3 (2020-10-23/ 2020-10-31)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862068; Age (years): 69; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL FROM BICYCLE	2020-10-04 (11)/ 2020-10-04 (11)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ LEFT RIB PAIN S/P	2020-10-04 (11)/ 2020-11-09 (47)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862088; Age (years): 67; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	2020-10-19 (25)/ 2020-11-19 (56)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862095; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Blastocystis infection/ BLASTOCYSTOSIS	2020-09-12 (13)/ 2020-09-19 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862098; Age (years): 45; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ NEW HTN DIAGNOSIS	2020-09-29 (30)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862137; Age (years): 82; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA RASH	2020-10-29 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862144; Age (years): 53; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Perirectal abscess/ PERIRECTAL ABSCESS	2020-11-04 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862155; Age (years): 50; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression/ DEPRESSION	2020-10-28 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3862155; Age (years): 50; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ RIGHT LOWER BACK PAIN	2020-10-30 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3862160; Age (years): 31; Sex: M; Race: ASIAN							
Infections and infestations/ Viral infection/ VIRAL LIKE ILLNESS	2020-11-21 (45)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862162; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Reproductive system and breast disorders/ Dysfunctional uterine bleeding/ EXACERBATION OF DYSFUNCTIONAL UTERINE BLEEDING	2020-09-13 (4)/ 2020-09-18 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862172; Age (years): 32; Sex: F; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Costochondritis/ COSTOCHONDRITIS	2020-10-27 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862211; Age (years): 39; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Paronychia/ INFECTED INGROWN LEFT HALLUX TOE	2020-11-02 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862246; Age (years): 44; Sex: F; Race: MULTIPLE: (b) (6)							
Injury, poisoning and procedural complications/ Tooth fracture/ TOOTH FRACTURE	2020-10-13 (19)/ 2020-10-16 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862263; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-11-08 (13)/ 2020-11-16 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872002; Age (years): 64; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING RIGHT SIDE LOW BACK PAIN	2020-08-04 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3872017; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ BILATERAL EAR INFECTION	2020-09-09 (9)/ 2020-09-19 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872031; Age (years): 57; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ RIGHT FOOT TENDONITIS	2020-09-05 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3872033; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-08-26 (23)/ 2020-08-28 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Bronchitis/ WORSENING OF BRONCHITIS	2020-08-29 (26)/ 2020-09-05 (33)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872043; Age (years): 73; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Scar/ ABNORMAL BREAST SCAR TISSUE	2020-09-10 (10)/ 2020-09-10 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872049; Age (years): 66; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermal cyst/ SEBACEOUS CYST ON LEFT BUTTOCK	2020-08-09 (5)/ 2020-08-12 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3872062; Age (years): 61; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-12 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Pain/ GENERALIZED BODY ACHES	2020-10-10 (39)/ 2020-10-23 (52)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872062; Age (years): 61; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872062; Age (years): 61; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872062; Age (years): 61; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-12 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-10-12 (41)/ 2020-10-21 (50)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Psychiatric disorders/ Confusional state/ CONFUSION	2020-10-18 (47)/ 2020-10-19 (48)	Yes/ Yes/ No	4	Yes/3 (2020-10-18/ 2020-10-23)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-10-18 (47)/ 2020-10-23 (52)	Yes/ Yes/ No	4	Yes/3 (2020-10-18/ 2020-10-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872062; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Sepsis/ SEPSIS	2020-10-18 (47)/ 2020-10-23 (52)	Yes/ Yes/ No	4	Yes/3 (2020-10-18/ 2020-10-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-18 (47)/ 2020-10-23 (52)	Yes/ Yes/ No	4	Yes/3 (2020-10-18/ 2020-10-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-10-23 (52)/ 2020-11-08 (68)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872067; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ LOCALIZE MUSCULOSKELETAL DISCOMFORT CHEST	2020-08-15 (10)/ 2020-08-17 (12)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872138; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-27 (17)/ 2020-09-08 (29)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-08-31 (21)/ 2020-08-31 (21)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Retching/ DRY HEAVES	2020-08-31 (21)/ 2020-08-31 (21)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3872191; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ ACUTE BRONCHITIS	2020-09-10 (28)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872191; Age (years): 57; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-19 (37)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3872223; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 DIAGNOSIS	2020-09-28 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ COVID-19 pneumonia/ LEFT LOWER LOBE PNEUMONIA DUE TO COVID 19 INFECTION	2020-09-30 (15)/ 2020-10-04 (19)	Yes/ Yes/ No		No		NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872228; Age (years): 76; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-08 (21)/ 2020-09-19 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872229; Age (years): 71; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-26 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3872253; Age (years): 30; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY ADENITIS OF THE HEAD AND NECK	2020-08-26 (6)/ 2020-09-23 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-28 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Gingivitis/ WORESNING OF GINGIVITIS	2020-09-03 (14)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872256; Age (years): 41; Sex: M; Race: ASIAN							
Gastrointestinal disorders/ Flatulence/ FLATULENCE	2020-09-15 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3872277; Age (years): 65; Sex: M; Race: WHITE							
Product issues/ Device breakage/ BROKEN DENTAL BRIDGE	2020-10-20 (21)/ 2020-10-23 (24)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3872324; Age (years): 41; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-10-11 (3)/ 2020-10-11 (3)	Yes/ Yes/ No	4	Yes/4	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECTS RIGHT FOOT IS IN A BOOT FOLLOWING SURGICAL REPAIR PROCEDURE

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872324; Age (years): 41; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ankle fracture/ CHIPPED BONE IN RT ANKLE	2020-10-11 (3)/ 2020-10-15 (7)	Yes/ Yes/ No	4	Yes/4	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Ligament rupture/ TORN LIGAMENTS IN RIGHT ANKLE	2020-10-11 (3)/ 2020-10-15 (7)	Yes/ Yes/ No	4	Yes/4	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3872334; Age (years): 63; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF LEFT SHOULDER ULNOHUMERAL ARTHRITIS	2020-09-22 (27)/ 2020-09-23 (28)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872384; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Gingivitis/ GUM INFECTION	2020-10-05 (36)/ 2020-10-14 (45)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872385; Age (years): 26; Sex: F; Race: ASIAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-30 (22)/ 2020-11-11 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872402; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ RIGHT FOOT FRACTURE (DUE TO MOTOR VEHICLE ACCIDENT)	2020-11-03 (36)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-03/ 2020-11-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3872462; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-14 (11)/ 2020-09-21 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872492; Age (years): 22; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Vulvovaginal discomfort/ VAGINAL IRRITATION	2020-09-22 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3872508; Age (years): 64; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK ACHE	2020-11-11 (24)/ 2020-11-15 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Renal and urinary disorders/ Chromaturia/ DARK URINE	2020-11-11 (24)/ 2020-11-15 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3882006; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Postoperative wound infection/ RIGHT CHEST INCISION INFECTION	2020-09-17 (10)/ 2020-10-17 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3882006; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-10-05 (28)/ 2020-10-15 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3882009; Age (years): 63; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Hepatic cancer/ MALIGNANT NEOPLASM OF LIVER	2020-10-01 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3882032; Age (years): 65; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-11-18 (27)/ 2020-11-18 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3892024; Age (years): 44; Sex: M; Race: WHITE							
Infections and infestations/ Respiratory tract infection/ ACUTE RESPIRATORY INFECTION	2020-10-30 (31)/ 2020-11-05 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3892032; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-09-29 (2)/ 2020-10-12 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ RASH ON MID BACK (URTICARIA)	2020-11-12 (46)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	

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Subject ID: US3892032; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-11-14 (48)/ 2020-11-19 (53)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/	RECOVERED/ RESOLVED
Subject ID: US3892052; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Vulvovaginal mycotic infection/ CANDIDAL VULVOVAGINITIS	2020-09-07 (4)/ 2020-09-17 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3892071; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-31 (25)/ 2020-11-05 (30)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3892076; Age (years): 59; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Dyslipidaemia/ DYSLIPIDEMIA	2020-10-29 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	
Vascular disorders/ Hypertensive urgency/ HYPERTENSIVE URGENCY	2020-10-29 (21)/ 2020-11-01 (24)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/	RECOVERED/ RESOLVED
Subject ID: US3892077; Age (years): 23; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-12 (2)/ 2020-09-16 (6)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3902015; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID-19	2020-10-26 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3902045; Age (years): 64; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-07 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3902064; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-15 (6)/ 2020-09-25 (16)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN - LUMBAR	2020-10-12 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-28 (49)/ 2020-11-06 (58)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3902064; Age (years): 50; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Feeling abnormal/ BRAIN FOG	2020-10-28 (49)/ 2020-11-06 (58)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Malaise/ MALAISE	2020-10-28 (49)/ 2020-11-06 (58)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-28 (49)/ 2020-11-06 (58)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3902100; Age (years): 22; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-10-18 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3902102; Age (years): 65; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Diabetes mellitus/ WORSENING OF DIABETES	2020-10-08 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3902127; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Oral herpes/ COLD SORE	2020-11-03 (20)/ 2020-11-10 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912006; Age (years): 71; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ SORE RIGHT PALM	2020-09-10 (16)/ 2020-10-05 (41)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912007; Age (years): 66; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ WORSENING OF CONGESTIVE HEART FAILURE	2020-09-24 (30)/ 2020-10-23 (59)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912007; Age (years): 66; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-24 (30)/ 2020-10-23 (59)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912017; Age (years): 66; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION, RIGHT INDEX FINGER	2020-10-04 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3912020; Age (years): 57; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY RASH (BOTH ARMS AND ABDOMEN)	2020-11-16 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3912021; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-09-18 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912046; Age (years): 59; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION (WORSENING OF)	2020-09-08 (9)/ 2020-09-24 (25)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912051; Age (years): 68; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Cold sweat/ COLD SWEATS	2020-09-14 (15)/ 2020-09-14 (15)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Seborrhoeic dermatitis/ SEBORRHEIC DERMATITIS	2020-10-14 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912099; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-21 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912103; Age (years): 68; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-02 (29)/ 2020-10-09 (36)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912111; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site lymphadenopathy/ INJECTION SITE LEFT AXILLARY LYMPHADENOPATHY	2020-10-11 (11)/ 2020-10-15 (15)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Axillary pain/ PAIN LEFT ARMPIT	2020-10-11 (11)/ 2020-10-21 (21)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912111; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN, LEFT SHOULDER	2020-10-11 (11)/ 2020-10-21 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912117; Age (years): 32; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Tonsillolith/ TONSILLOLITHS	2020-10-16 (15)/ 2020-10-19 (18)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912119; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-10-08 (3)/ 2020-10-23 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912119; Age (years): 55; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pneumonitis/ POSSIBLE LUNG INFLAMMATION	2020-10-12 (7)/ 2020-10-21 (16)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dysphonia/ HOARSE	2020-10-13 (8)/ 2020-10-18 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3912129; Age (years): 22; Sex: F; Race: WHITE							
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-10-01 (24)/ 2020-10-04 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912141; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Ear infection/ RIGHT EAR INFECTION	2020-11-05 (24)/ 2020-11-08 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912160; Age (years): 26; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ ACNE	2020-11-04 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3912171; Age (years): 21; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING OF ANXIETY	2020-10-13 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-10-13 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912219; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-10-07 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-07 (10)/ 2020-11-10 (13)	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-11-07 (10)/ 2020-11-10 (13)	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Colitis/ COLITIS	2020-11-07 (10)/ 2020-11-19 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912241; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Asthenia/ GENERALIZED WEAKNESS	2020-11-03 (23)/ Ongoing	Yes/ Yes/ No	4	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ CHEST PAIN (PLEURAL)	2020-11-03 (23)/ 2020-11-05 (25)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM, LLL	2020-11-03 (23)/ 2020-11-09 (29)	Yes/ Yes/ No	4	Yes/3 (2020-11-04/ 2020-11-05)	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3922005; Age (years): 64; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-08-18 11:32 (1)/ 2020-08-28 (11)	No/ Yes/ No	1	No	NA/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3922029; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Wound infection/ INFECTION RIGHT ANKLE (ABRASION)	2020-10-16 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3922046; Age (years): 62; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ BROKEN TOOTH RIGHT LOWER MOLAR	2020-10-05 (11)/ 2020-10-05 (11)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Arrhythmia/ ARRYTHMIA	2020-10-30 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3922046; Age (years): 62; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	2020-10-30 (36)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3922067; Age (years): 77; Sex: F; Race: WHITE							
Psychiatric disorders/ Confusional state/ CONFUSION	2020-09-07 (7)/ 2020-09-09 (9)	Yes/ Yes/ No	3	Yes/3 (2020-09-07/ 2020-09-09)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3922087; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ Folliculitis/ WORSENING FOLLICULITIS BILATERAL CHEST	2020-09-26 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3922096; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-01 (23)/ 2020-10-26 (48)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3922118; Age (years): 53; Sex: M; Race: WHITE							
Infections and infestations/ Skin bacterial infection/ RIGHT ARM BACTERIA SKIN INFECTION	2020-10-23 (8)/ 2020-11-02 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE RIGHT WRIST	2020-11-08 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932005; Age (years): 79; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Hiatus hernia/ HIATAL HERNIA	2020-10-20 (30)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-20/ 2020-10-22)	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932025; Age (years): 51; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ FLU LIKE SYMPTOMS - NASAL CONGESTION	2020-10-11 (16)/ 2020-10-16 (21)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3932025; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ FLU LIKE SYMPTOM - BODY ACHES	2020-10-11 (16)/ 2020-10-20 (25)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3932066; Age (years): 78; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-11-20 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932083; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 POSITIVE	2020-11-14 (38)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-16/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3932099; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-30 (14)/ 2020-11-01 (16)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3932100; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-26 (20)/ 2020-11-08 (33)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3932147; Age (years): 84; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ BODY ACHES/ MUSCLE ACHES	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3932147; Age (years): 84; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ CONGESTION/ RUNNY NOSE	2020-09-20 (5)/ 2020-09-27 (12)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932147; Age (years): 84; Sex: F; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ WORSENING OF CONGESTIVE HEART FAILURE	2020-10-05 (20)/ 2020-10-11 (26)	Yes/ Yes/ No	4	Yes/3 (2020-10-05/ 2020-10-11)/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ EXACERBATED COPD CAUSED BY WORSENING CONGESTIVE HEART FAILURE	2020-10-05 (20)/ 2020-11-05 (51)	Yes/ Yes/ No	4	Yes/3 (2020-10-05/ 2020-10-11)/6	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3932182; Age (years): 62; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Pulmonary mass/ NODULE ON RT LUNG	2020-10-26 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3932182; Age (years): 62; Sex: F; Race: MULTIPLE:				(b) (6)			
Musculoskeletal and connective tissue disorders/ Cervical spinal stenosis/ C5-C6 SEVERE LEFT CANAL STENOSIS	2020-10-26 (7)/ 2020-11-17 (29)	Yes/ Yes/ No	3	Yes/3 (2020-10-26/ 2020-10-28)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3942104; Age (years): 50; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Ear pain/ OTALGIA	2020-09-29 (8)/ 2020-10-01 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3942126; Age (years): 70; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Dental caries/ DENTAL CARRIES	2020-09-23 (3)/ 2020-09-23 (3)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3942128; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Gastroenteritis viral/ UNSPECIFIED STOMACH VIRUS	2020-10-15 (25)/ 2020-10-17 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3952033; Age (years): 52; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Food poisoning/ FOOD POISONING	2020-09-23 (22)/ 2020-09-30 (29)	Yes/ Yes/ No	3	Yes/3 (2020-09-23/ 2020-09-30)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-10-06 (35)/ 2020-10-25 (54)	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Cardiac disorders/ Pericarditis/ PERICARDITIS	2020-10-31 (60)/ 2020-11-03 (63)	Yes/ Yes/ No	3	Yes/3 (2020-10-31/ 2020-11-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3952071; Age (years): 50; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-21 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962004; Age (years): 46; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY	2020-11-05 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3962006; Age (years): 73; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-09-08 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	
Subject ID: US3962066; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Oedema peripheral/ FLUID RETENTION (EDEMA) IN LEGS	2020-09-30 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3962079; Age (years): 61; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-10-06 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962113; Age (years): 19; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID - 19	2020-11-20 (3)/ Ongoing	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3972023; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Nasopharyngitis/ COMMON COLD	2020-10-17 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3972041; Age (years): 30; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ COVID-19/ COVID 19 INFECTION	2020-11-02 (40)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3972049; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION COMPLICATED	2020-11-15 (48)/ 2020-11-20 10:00 (52)	Yes/ Yes/ No	2	Yes/3 (2020-11-15/ 2020-11-20)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3972070; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ear injury/ PERFORATED (R) EAR	2020-10-29 (32)/ 2020-11-04 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3972149; Age (years): 21; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 INFECTION	2020-10-22 (7)/ 2020-10-29 (14)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3972155; Age (years): 51; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID-19	2020-10-20 (8)/ 2020-10-24 (12)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3972205; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Musculoskeletal disorder/ EXACERBATION OF CHRONIC MUSCULOSKELETAL ISSUES INVOLVING NECK AND LEFT SHOULDER	2020-11-10 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3982012; Age (years): 43; Sex: F; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-09-11 (17)/ 2020-09-18 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3982017; Age (years): 62; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-19 (27)/ 2020-11-01 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982031; Age (years): 86; Sex: F; Race: WHITE							
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-09-10 (15)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-25/ 2020-09-26)/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3982072; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS RIGHT ANTECUBITAL	2020-10-04 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3982109; Age (years): 30; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ LEFT INTERCOSTAL MUSCLE STRAIN	2020-09-22 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982143; Age (years): 44; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ RIGHT LOWER MOLAR TOOTH PAIN	2020-10-23 (10)/ 2020-11-09 (27)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3982180; Age (years): 32; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	2020-09-16 12:27 (1)/ 2020-09-16 12:33 (1)	No/ Yes/ No	1	No	NA/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3982275; Age (years): 63; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Idiopathic urticaria/ IDIOPATHIC URTICARIA	2020-10-21 (8)/ 2020-10-21 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3992010; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ COVID-19/ COVID 19	2020-11-12 (23)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992019; Age (years): 22; Sex: M; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORETHROAT	2020-10-13 (22)/ 2020-10-15 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-13 (22)/ 2020-10-16 (25)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-13 (22)/ 2020-10-17 (26)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-14 (23)/ 2020-10-17 (26)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992019; Age (years): 22; Sex: M; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ DRY COUGH	2020-10-14 (23)/ 2020-10-17 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3992040; Age (years): 28; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-16 (21)/ 2020-10-29 (34)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 (21)/ 2020-10-29 (34)	Yes/ Yes/ Yes	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992040; Age (years): 28; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-16 (21)/ 2020-10-29 (34)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-16 (21)/ 2020-10-29 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORETHROAT	2020-10-16 (21)/ 2020-10-29 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992040; Age (years): 28; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-16 (21)/ 2020-10-29 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-20 (25)/ 2020-10-29 (34)	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3992064; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-21 (17)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-21 (17)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992064; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHES	2020-10-21 (17)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-21 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-21 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-21 (17)/ 2020-10-30 (26)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992064; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-21 (17)/ 2020-10-30 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002027; Age (years): 64; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash maculo-papular/ MACULOPAPULAR RASH ON NECK (NON-URTICARIAL)	2020-09-05 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002033; Age (years): 46; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Adnexal torsion/ LEFT OVARIAN TORSION	2020-08-01 (5)/ 2020-08-01 (5)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-09-18 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002036; Age (years): 64; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	2020-08-17 00:00 (20)/ 2020-08-22 00:00 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-16 (21)/ 2020-09-23 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002059; Age (years): 44; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ CONTUSION TO THE RIGHT KNEE	2020-09-07 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3002081; Age (years): 33; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-15 (77)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002111; Age (years): 55; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-17 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002146; Age (years): 23; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-12 00:00 (1)/ 2020-08-17 00:00 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002158; Age (years): 43; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-11 09:08 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002160; Age (years): 41; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ WORSENING OF HYPERLIPIDEMIA	2020-09-13 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002207; Age (years): 45; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin lesion/ RIGHT SCALP LESION	2020-09-09 (13)/ 2020-09-09 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3002218; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Eye infection/ BILATERAL EYE INFECTION	2020-10-01 (3)/ 2020-10-07 (9)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3002233; Age (years): 61; Sex: F; Race: WHITE							
Renal and urinary disorders/ Hypertonic bladder/ OVERACTIVE BLADDER	2020-11-04 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3002256; Age (years): 31; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Tonsillolith/ TONSILLOLITH	2020-09-25 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3002276; Age (years): 70; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-30 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012004; Age (years): 64; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bursitis/ LEFT KNEE BURSITIS	2020-08-16 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012021; Age (years): 46; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASIL CELL CARCINOMA (SCALP)	2020-09-22 (28)/ 2020-09-22 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012023; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-08-06 (10)/ 2020-08-10 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE, LEFT ARM	2020-08-25 21:00 (1)/ 2020-09-02 (9)	Yes/ Yes/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Investigations/ Heart rate irregular/ IRREGULAR HEART RATE	2020-08-26 16:00 (2)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012026; Age (years): 70; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Meniscus injury/ LEFT KNEE MENISCUS TEAR	2020-08-18 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012036; Age (years): 81; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-05 (40)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012038; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Paronychia/ GREAT TOE INGROWN TOENAIL INFECTION	2020-08-19 (20)/ 2020-08-26 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012053; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE, LEFT ARM	2020-08-06 16:00 (1)/ 2020-08-26 (21)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3012068; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-09-18 (16)/ 2020-09-24 (22)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012069; Age (years): 72; Sex: M; Race: WHITE							
Investigations/ Glycosylated haemoglobin increased/ A1C INCREASE	2020-10-01 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Cellulitis/ PAIN DUE TO CELLULITIS IN LEFT FOOT	2020-10-23 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012070; Age (years): 53; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ ACHILLES TENDINITIS, BILATERAL	2020-08-27 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012070; Age (years): 53; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Breast cyst/ LEFT BREAST CYST	2020-09-29 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012098; Age (years): 60; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Colitis/ COLITIS	2020-09-24 (17)/ 2020-09-30 (23)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Cardiac failure congestive/ EXACERBATION OF DIASTOLIC CHF	2020-09-29 (22)/ 2020-10-12 (35)	Yes/ Yes/ No	3	Yes/3 (2020-09-29/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ ACUTE HYPOXIC RESPIRATORY FAILURE	2020-09-29 (22)/ 2020-10-12 (35)	Yes/ Yes/ No	4	Yes/3 (2020-09-29/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012098; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Clostridium difficile infection/ CLOSTRICFIUM DIFFICILE	2020-09-29 (22)/ 2020-10-25 (48)	Yes/ Yes/ No	3	Yes/3 (2020-09-26/ 2020-10-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012130; Age (years): 46; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ WORSENING OF DENTAL CARY - TOP RIGHT CANINE	2020-10-06 (27)/ 2020-10-06 (27)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Tooth fracture/ WORSENING OF CHIPPED TOOTH BOTOM LEFT 1ST MOLAR	2020-10-06 (27)/ 2020-10-06 (27)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012130; Age (years): 46; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ TOOTH EXTRACTION PAIN	2020-10-09 (30)/ 2020-10-10 (31)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Gonorrhoea/ GONORRHEA	2020-11-05 (57)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012159; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-25 (12)/ 2020-10-05 (22)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012174; Age (years): 55; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-01 (15)/ 2020-09-05 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012185; Age (years): 71; Sex: M; Race: WHITE							
Investigations/ Blood cholesterol increased/ WORSENING OF HIGH CHOLESTEROL	2020-11-11 (55)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012186; Age (years): 73; Sex: F; Race: WHITE							
Nervous system disorders/ Peripheral sensory neuropathy/ WORSENING OF NEUROPATHY SENSORY	2020-10-02 (15)/ 2020-10-23 (36)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ UTI	2020-10-08 (21)/ 2020-10-12 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012242; Age (years): 53; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2020-10-06 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012242; Age (years): 53; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-11-05 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3012267; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABSCESSED TOOTH	2020-09-08 (6)/ 2020-09-14 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012293; Age (years): 44; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-26 (18)/ 2020-10-29 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3012309; Age (years): 64; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin lesion/ RAISED, RED SKIN LESION L ARM	2020-11-09 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3012310; Age (years): 62; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-10-23 (12)/ 2020-11-09 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022006; Age (years): 67; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-08-07 (12)/ 2020-09-05 (41)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022011; Age (years): 70; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiac failure/ MILD CARDIAC INSUFFIECNCY	2020-11-13 (82)/ 2020-11-13 (82)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022012; Age (years): 35; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-07-27 08:00 (1)/ 2020-09-15 (51)	No/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022020; Age (years): 63; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Intraductal proliferative breast lesion/ DUCTAL CARCINOMA INSITUU LEFT BREAST	2020-10-16 (54)/ 2020-11-13 (82)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022021; Age (years): 65; Sex: F; Race: WHITE							
Vascular disorders/ Orthostatic hypotension/ ORTHOSTATIC HYOTENSION	2020-09-14 (48)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022031; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Pneumonia/ PNUEMONIA	2020-08-10 (15)/ 2020-08-19 (24)	Yes/ Yes/ No	4	Yes/3 (2020-08-10/ 2020-08-19)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022031; Age (years): 66; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Overdose/ OVERDOSE OF KLONOPIN	2020-08-10 (15)/ 2020-08-19 (24)	Yes/ Yes/ No	4	Yes/3 (2020-08-10/ 2020-08-19)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ LUNG FAILURE	2020-08-10 (15)/ 2020-08-19 (24)	Yes/ Yes/ No	4	Yes/3 (2020-08-10/ 2020-08-19)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022033; Age (years): 39; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-31 (68)/ 2020-11-01 (69)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-31 (68)/ 2020-11-02 (70)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022033; Age (years): 39; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-31 (68)/ 2020-11-02 (70)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES ALL OVER	2020-10-31 (68)/ 2020-11-02 (70)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER	2020-10-31 (68)/ 2020-11-02 (70)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-31 (68)/ 2020-11-02 (70)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022033; Age (years): 39; Sex: F; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-31 (68)/ 2020-11-02 (70)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022044; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF BACK PAIN	2020-10-02 (39)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022049; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-08-24 (28)/ 2020-09-22 (57)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Hordeolum/ HORDEOLUM RIGHT EYE	2020-08-24 10:00 (27)/ 2020-09-03 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022049; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-07 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Reproductive system and breast disorders/ Uterine polyp/ UTERINE POLYPS	2020-10-07 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Nephrolithiasis/ NEPHROLITHIASIS	2020-10-07 (41)/ 2020-10-11 (45)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022052; Age (years): 55; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Oesophageal carcinoma/ ESOPHAGEAL CANCER	2020-10-15 (35)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022062; Age (years): 49; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-13 (47)/ 2020-10-20 (54)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-13 (47)/ 2020-10-20 (54)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-13 (47)/ 2020-10-22 (56)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-13 (47)/ 2020-10-28 (62)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022067; Age (years): 80; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-02 (69)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022103; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-08-14 (15)/ 2020-08-17 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain upper/ INTERMITTENT EPIGASTRIC PAIN	2020-08-16 (17)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-08-16/ 2020-08-17)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Investigations/ Hepatic enzyme increased/ ELEVATED LIVER ENZYMES	2020-08-17 (18)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022108; Age (years): 32; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Cervical dysplasia/ LOW GRADE SQUAMOUS INTRAEPITHELIAL LESION	2020-08-26 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022135; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ DENTAL INFECTION	2020-10-02 (19)/ 2020-10-05 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022140; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ LOWER BACK SPASMS	2020-09-21 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022167; Age (years): 21; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-10-05 (22)/ 2020-10-08 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022167; Age (years): 21; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Gastritis/ ACUTE GASTITIS	2020-10-14 (31)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022192; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING OF RIGHT SHOULDER PAIN	2020-08-25 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3022193; Age (years): 70; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Ovarian cyst/ OVARIAN CYSTS (RIGHT)	2020-09-17 05:00 (28)/ 2020-10-07 11:00 (48)	Yes/ Yes/ No	2	Yes/3 (2020-10-06/ 2020-10-07)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022194; Age (years): 36; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-17 (31)/ 2020-10-23 (37)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-17 (31)/ 2020-10-24 (38)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022202; Age (years): 47; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-24 (36)/ 2020-09-25 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-24 (36)/ 2020-09-25 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022202; Age (years): 47; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-24 (36)/ 2020-09-25 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022208; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE	2020-09-10 (22)/ 2020-09-14 (26)	Yes/ Yes/ No	4	Yes/3 (2020-09-10/ 2020-09-14)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: DUE TO CONGESTIVE HEART FAILURE IS A NEW DIAGNOSIS.
Subject ID: US3022216; Age (years): 83; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF BACK PAIN	2020-09-08 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022220; Age (years): 47; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-13 (25)/ 2020-09-18 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-15 (10)/ 2020-10-22 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 (10)/ 2020-10-22 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-15 (10)/ 2020-10-22 (17)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022246; Age (years): 62; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF LEFT HIP ARRHRITIS	2020-11-14 (52)/ 2020-11-15 (53)	Yes/ Yes/ No	4	Yes/3 (2020-11-14/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022252; Age (years): 77; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm malignant/ CARCINOME FOREHEAD	2020-09-24 (7)/ 2020-09-24 (7)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-09 (53)/ 2020-11-11 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022252; Age (years): 77; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-09 (53)/ 2020-11-11 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3022253; Age (years): 46; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-10-04 (11)/ 2020-10-16 (23)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3022254; Age (years): 63; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-09-24 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3022274; Age (years): 37; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-11-10 (54)/ 2020-11-10 (54)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022276; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
Injury, poisoning and procedural complications/ Back injury/ WORSENING OF BACK INJURY	2020-10-02 (9)/ 2020-10-03 (10)	Yes/ Yes/ No	2	Yes/3 (2020-10-02/ 2020-10-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3022322; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Endocrine disorders/ Hypothyroidism/ HYPOTHYROIDISM	2020-10-07 (14)/ 2020-10-07 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: DUE TO HYPOTHYROIDISM BEING A PART OF MEDICAL HISTORY NOW.
Subject ID: US3022336; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS SORE THROAT	2020-11-03 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3022336; Age (years): 46; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT ANTERIOR CHAIN CERVICAL LYMPHADEMOPATHY	2020-11-04 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032007; Age (years): 48; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Immune system disorders/ Seasonal allergy/ SEASONAL ALLERGIES	2020-10-01 (24)/ 2020-11-06 (60)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032010; Age (years): 25; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-09-16 (23)/ 2020-10-20 (57)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032012; Age (years): 58; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ WORSENING OF GASTROESOPHAGEAL REFLUX DISEASE	2020-08-14 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032016; Age (years): 32; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ HORMONAL ACNE OF THE FACE	2020-08-11 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Pharyngitis streptococcal/ STREPTOCOCCAL PHARYNGITIS	2020-08-24 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032016; Age (years): 32; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ WORSENING FACIAL ACNE	2020-10-02 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3032036; Age (years): 26; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ ADULT FACIAL ACNE	2020-09-03 (9)/ 2020-09-13 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032042; Age (years): 52; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ CERVICALGIA (NECK PAIN)	2020-08-10 (13)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-10 (13)/ 2020-08-24 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032052; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-26 (27)/ 2020-10-08 (39)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032056; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-09 (8)/ 2020-09-14 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032066; Age (years): 50; Sex: M; Race: WHITE							
Psychiatric disorders/ Major depression/ MAJOR DEPRESSIVE DISORDER WITH SEASONAL PATTERN	2020-08-20 (18)/ 2020-09-30 (59)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032078; Age (years): 47; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-10-05 (35)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032079; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS	2020-09-05 (33)/ 2020-09-15 (43)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3032080; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-10-14 (43)/ 2020-10-20 (49)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032100; Age (years): 60; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ SPRAIN OF MUSCLE IN LOWER BACK	2020-08-23 (19)/ 2020-08-30 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032103; Age (years): 38; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS	2020-10-30 (57)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032131; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ Diverticulitis/ WORSENING OF DIVERTICULITIS	2020-09-14 (7)/ 2020-09-21 (14)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032137; Age (years): 36; Sex: M; Race: WHITE							
Infections and infestations/ Staphylococcal skin infection/ STAPHYLOCOCCUS AUREUS INFECTION TO RIGHT CHEEK	2020-09-13 (5)/ 2020-09-23 (15)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3032160; Age (years): 35; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bursitis/ BURSITIS LEFT HIP	2020-09-08 (32)/ 2020-09-21 (45)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032160; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-14 (6)/ 2020-09-21 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Pharyngitis streptococcal/ STREPTOCOCCAL PHARYNGITIS	2020-11-19 (72)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3032192; Age (years): 54; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Actinic keratosis/ WORSENING OF ACTINIC KERATOSIS ON RIGHT SIDE OF FOREHEAD	2020-09-04 (25)/ 2020-09-04 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032208; Age (years): 65; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo positional/ BENIGN POSITIONAL VERTIGO	2020-08-28 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032223; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Asymptomatic COVID-19/ COVID-19 ASYMPTOMATIC	2020-10-17 (25)/ 2020-10-17 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3032228; Age (years): 59; Sex: M; Race: WHITE							
Cardiac disorders/ Angina pectoris/ WORSENING OF CARDIAC ANGINA	2020-10-15 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032254; Age (years): 54; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-09-02 (15)/ 2020-10-12 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032255; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-16 (62)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3032260; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTION IN RIGHT HAND	2020-11-10 (51)/ Ongoing	Yes/ Yes/ No	1	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3032284; Age (years): 71; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-09 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3032297; Age (years): 39; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ BITTEN OR STUNG BY NONVENOMOUS INSECT OR ARTHROPED	2020-09-05 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Fibromyalgia/ FIBROMYALGIA	2020-09-09 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3032305; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-09-08 (19)/ 2020-09-08 (19)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3032313; Age (years): 49; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ BROKEN LEFT FOOT	2020-10-01 (42)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042001; Age (years): 69; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ DEPRESSION	2020-09-25 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042032; Age (years): 81; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ EXACERBATION OF CHRONIC DYSPNEA	2020-08-27 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042042; Age (years): 55; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-09-17 (16)/ 2020-09-21 (20)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042056; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-15 (16)/ 2020-09-22 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042060; Age (years): 69; Sex: M; Race: WHITE							
Vascular disorders/ Essential hypertension/ ESSENTIAL HYPERTENSION	2020-08-14 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042074; Age (years): 32; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-08-17 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042090; Age (years): 55; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING RIGHT KNEE PAIN INDUCED BY OSTEOARTHRITIS	2020-08-20 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042093; Age (years): 24; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-08-18 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042107; Age (years): 35; Sex: M; Race: WHITE							
Infections and infestations/ Folliculitis/ CHIN FOLLICULITIS	2020-08-21 (15)/ 2020-08-28 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis bacterial/ BACTERIAL SINUSITIS	2020-10-12 (33)/ 2020-10-16 (37)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042116; Age (years): 26; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ ACID RELUX	2020-08-26 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042119; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-28 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042138; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-10 (3)/ 2020-09-20 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042142; Age (years): 29; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Patella fracture/ RIGHT PATELLA FRACTURE	2020-09-28 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3042151; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Rash pustular/ RASH ON TORSO-PUSTULAR; NON-URTICARIAL	2020-10-05 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042188; Age (years): 70; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-25 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042190; Age (years): 27; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ MULTIPLE PULMONARY EMBOLI	2020-09-09 (28)/ 2020-09-10 (29)	Yes/ Yes/ No	2	Yes/3 (2020-09-09/ 2020-09-10)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042192; Age (years): 40; Sex: M; Race: WHITE							
Investigations/ Hepatic enzyme increased/ ELEVATED LIVER ENZYMES	2020-08-31 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3042202; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-09-21 (11)/ 2020-10-01 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042219; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ DENTAL INFECTION	2020-09-07 (22)/ 2020-09-11 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042222; Age (years): 34; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tendon injury/ LEFT HAND TENDON LACERATION	2020-09-04 (19)/ 2020-09-05 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Infections and infestations/ Cellulitis/ LEFT HAND CELLULITIS	2020-09-18 (5)/ 2020-09-28 (15)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042235; Age (years): 51; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Umbilical hernia/ UMBILICAL HERNIA	2020-09-15 08:00 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042247; Age (years): 27; Sex: F; Race: NOT REPORTED							
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-09-29 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042250; Age (years): 32; Sex: F; Race: OTHER: (b) (6)							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT DISORDER	2020-09-23 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042256; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Periodontitis/ RIGHT PERIODONTISTS	2020-09-03 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042262; Age (years): 22; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-11-01 (46)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042263; Age (years): 47; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-09-29 (13)/ 2020-10-08 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042265; Age (years): 46; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ MILD DIARRHEA	2020-10-06 (20)/ 2020-10-09 (23)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ SEVERE NAUSEA	2020-10-06 (20)/ 2020-10-09 (23)	Yes/ Yes/ No	3	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ MODERATE VOMITING	2020-10-06 (20)/ 2020-10-09 (23)	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042265; Age (years): 46; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ MILD COUGH	2020-10-06 (20)/ 2020-10-09 (23)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ MILD DYSPNEA	2020-10-06 (20)/ 2020-10-09 (23)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ MODERATE FATIGUE	2020-10-06 (20)/ 2020-10-10 (24)	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ SEVERE HEADACHE	2020-10-06 (20)/ 2020-10-10 (24)	Yes/ Yes/ No	3	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042265; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-10-08 (22)/ 2020-10-13 (27)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3042285; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTION TO 2ND TOE ON LEFT FOOT	2020-09-02 (13)/ 2020-09-21 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Investigations/ Vitamin K/ VITAMIN K	2020-11-03 (35)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3042291; Age (years): 63; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Rib fracture/ BROKEN RIBS	2020-09-01 (12)/ 2020-10-12 (53)	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3042291; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ TORN RIGHT ROTATOR CUFF	2020-09-01 (12)/ 2020-10-12 (53)	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3042320; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-09-01 (8)/ 2020-09-07 (14)	Yes/ Yes/ No	1	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Pharyngitis streptococcal/ STREP PHARYNGITIS	2020-11-03 (36)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3052014; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-08-25 18:00 (1)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Skin and subcutaneous tissue disorders/ Erythema/ LOCALIZED REDNESS	2020-08-25 18:00 (1)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3052028; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN NOS	2020-08-05 (7)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-08-05/ 2020-08-06)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3052039; Age (years): 70; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE AT TIME OF NP SWAB	2020-07-31 10:23 (1)/ 2020-07-31 00:00 (1)	No/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3052258; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEAD ACHE		Yes/ Yes/ Yes					
Respiratory, thoracic and mediastinal disorders/ Paranasal sinus discomfort/ SINUS PRESSURE		Yes/ Yes/ Yes					
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-02 (15)/	Yes/ Yes/ No					

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3052262; Age (years): 35; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Adverse drug reaction/ ADVERSE EFFECT OF DRUG	2020-09-18 19:00 (1)/ 2020-09-24 08:00 (6)	Yes/ Yes/ No	3	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062019; Age (years): 66; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-04 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Cellulitis/ CELLULITIS LEFT KNEE	2020-09-18 (22)/ 2020-09-26 (30)	Yes/ Yes/ No	4	Yes/3 (2020-09-22/ 2020-09-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: CONTINUES ON ANTIBIOTICS
Infections and infestations/ Joint abscess/ LEFT KNEE ABCESS	2020-09-22 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062019; Age (years): 66; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-09-22 (26)/ 2020-09-25 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Investigations/ Cardiac murmur/ HEART MURMUR RECURRENT	2020-09-23 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-24 (28)/ 2020-09-24 (28)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062033; Age (years): 41; Sex: M; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-10-08 (41)/ 2020-10-14 (47)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062033; Age (years): 41; Sex: M; Race: WHITE							
Infections and infestations/ Asymptomatic COVID-19/ ASYMPTOMATIC COVID19	2020-11-06 (70)/ 2020-11-06 (70)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3062035; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS, BILATERAL FEET	2020-08-30 18:00 (2)/ 2020-09-09 18:00 (12)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062047; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES GENERALIZED	2020-08-04 06:00 (1)/ 2020-08-12 23:00 (10)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062054; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-22 (23)/ 2020-09-29 (30)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062079; Age (years): 40; Sex: F; Race: WHITE							
Investigations/ Transaminases increased/ TRANSMINITIS	2020-09-07 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Renal and urinary disorders/ Hydronephrosis/ RIGHT HYDRONEPHROSIS	2020-09-07 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Renal and urinary disorders/ Ureterolithiasis/ RIGHT OBSTRUCTING URETERAL STONE	2020-09-07 (4)/ 2020-09-09 (6)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062079; Age (years): 40; Sex: F; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ WORSENING OF NEPHROLITHIASIS RECURRENT	2020-09-07 (4)/ 2020-09-10 (7)	Yes/ Yes/ No	4	Yes/3 (2020-09-07/ 2020-09-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural pain/ POST OP PAIN	2020-09-09 (6)/ 2020-09-16 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062085; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION LEFT HAND	2020-09-22 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062086; Age (years): 36; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-08-24 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062107; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Infected cyst/ INFECTED CYST, BACK	2020-08-14 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Clostridium difficile infection/ CLOSTRIDIUM DIFFICILE	2020-08-21 (17)/ 2020-09-01 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062108; Age (years): 58; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTH PAIN	2020-08-14 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062115; Age (years): 53; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-11 (39)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062120; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Ear infection/ BILATERAL EAR INFECTION	2020-09-14 (11)/ 2020-09-18 (15)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062142; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-24 (21)/ 2020-09-28 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062143; Age (years): 69; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Hand fracture/ OPEN FRACTURE RIGHT 2 DISTAL METATCARPOPPHALENGEAL	2020-09-28 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062151; Age (years): 72; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ LEFT HIP OSTEOARTHRITIS	2020-10-14 (41)/ 2020-10-15 (42)	Yes/ Yes/ No	4	Yes/3 (2020-10-14/ 2020-10-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Postoperative wound infection/ POST OP WOUND INFECTION	2020-10-20 (47)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-20/ 2020-10-28)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Procedural nausea/ POST OP NAUSEA RECURRENT	2020-10-20 (47)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Procedural pain/ POST OP PAIN	2020-10-20 (47)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062164; Age (years): 59; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ TYPE 2 DIABETES MELLITUS	2020-08-25 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062196; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-11-01 (54)/ 2020-11-11 (64)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062227; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-02 (53)/ 2020-11-09 (60)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062238; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-27 (44)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062247; Age (years): 75; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendon disorder/ SUBSCAPULAR TENDINOPATHY	2020-09-18 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3062250; Age (years): 39; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-20 (6)/ 2020-08-25 (11)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Psychiatric disorders/ Alcohol abuse/ WORSENING OF ALCOHOL ABUSE	2020-09-17 (34)/ 2020-09-23 (40)	Yes/ Yes/ No	4	Yes/3 (2020-09-17/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Pain/ GENERALIZED PAIN	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Infections and infestations/ Chronic sinusitis/ CHRONIC SINUSITIS	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Periorbital haematoma/ LEFT PERIORBITAL HEMATOMA	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Periorbital haemorrhage/ LEFT PERIORBITAL ECCHYMOSIS	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Skin laceration/ SCALP ABRASIONS	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Investigations/ Transaminases increased/ TRANSAMINITIS	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ RIGHT HIP DEGENERATIVE CHANGES	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ DEGENERATIVE SPONDYLOSIS	2020-10-13 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Alcohol poisoning/ ACUTE ALCOHOL INTOXICATION	2020-10-13 (21)/ 2020-10-14 (22)	Yes/ Yes/ No	4	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST PAIN - MUSCULOSKELETAL	2020-10-13 (21)/ 2020-10-14 (22)	Yes/ Yes/ No	4	Yes/3 (2020-10-13/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-13 (21)/ 2020-10-20 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Alcohol withdrawal syndrome/ ALCOHOL WITHDRAWAL SYMPTOMS	2020-10-13 (21)/ 2020-10-20 (28)	Yes/ Yes/ No	4	Yes/3 (2020-10-13/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	2020-10-13 (21)/ 2020-10-20 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Upper limb fracture/ LEFT ELBOW FRACTURE	2020-10-14 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-10-14 (22)/ 2020-10-14 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ GENERALIZED PAIN	2020-10-27 (35)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Clavicle fracture/ RIGHT DISTAL 3RD CLAVICLE FRACTURE	2020-10-27 (35)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Thoracic vertebral fracture/ T11 AND T12 END PLATE FRACTURE	2020-10-27 (35)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Alcohol poisoning/ ACUTE ALCOHOL INTOXICATION	2020-10-27 (35)/ 2020-10-28 (36)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	2020-10-27 (35)/ 2020-11-01 (40)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Psychiatric disorders/ Alcohol withdrawal syndrome/ ALCOHOL WITHDRAWAL SYMPTOMS	2020-10-27 (35)/ 2020-11-02 (41)	Yes/ Yes/ No	4	Yes/3 (2020-10-27/ 2020-11-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	2020-10-28 (36)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN, GENERALIZED	2020-10-28 (36)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-10-28 (36)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE							
Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	2020-10-28 (36)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	2020-10-28 (36)/ 2020-10-29 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3062292; Age (years): 28; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Injection site induration/ HARDNESS AT INJECTION SITE	2020-10-01 15:00 (1)/ 2020-10-09 19:00 (10)	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3062300; Age (years): 37; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ TINGLING IN ALL EXTREMITIES	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082005; Age (years): 64; Sex: M; Race: WHITE							
Eye disorders/ Dry age-related macular degeneration/ DRY MACULAR DEGENERATION (L EYE)	2020-09-23 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082016; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	2020-08-31 (21)/ 2020-09-06 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082020; Age (years): 36; Sex: F; Race: WHITE							
Hepatobiliary disorders/ Cholelithiasis/ GALLSTONES	2020-08-15 (4)/ 2020-08-25 (14)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3082030; Age (years): 50; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Erectile dysfunction/ ERECTILE DYSFUNCTION	2020-08-28 (15)/ 2020-08-28 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082051; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Sepsis/ SEPSIS	2020-08-26 (9)/ 2020-08-26 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Pancreatitis acute/ ACUTE PANCREATITIS	2020-08-26 (9)/ 2020-09-30 (44)	Yes/ Yes/ No	4	Yes/3 (2020-08-26/ 2020-09-30)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082051; Age (years): 66; Sex: M; Race: WHITE							
Hepatobiliary disorders/ Bile duct stone/ CHOLEDOCHOLITHIASIS	2020-08-26 (9)/ 2020-09-30 (44)	Yes/ Yes/ No	4	Yes/3 (2020-08-26/ 2020-09-30)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Benign hepatic neoplasm/ RIGHT POSTERIOR BENIGN LIVER LESION	2020-08-27 (10)/ 2020-09-30 (44)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082069; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ Skin infection/ SKIN INFECTION [RIGHT GLUTE]	2020-09-11 (23)/ 2020-09-24 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082081; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bursitis/ BURSITIS [RIGHT ARM/SHOULDER]	2020-09-10 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2020-10-02 (12)/ 2020-10-19 (29)	Yes/ Yes/ No	3	Yes/3 (2020-10-02/ 2020-10-05)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Constipation/ CONSTIPATION	2020-10-05 (15)/ 2020-11-04 (45)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082087; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-16 (27)/ 2020-09-21 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082094; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-06 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3082101; Age (years): 62; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Uterine leiomyoma/ WORSENING OF UTERINE FIBROIDS	2020-09-15 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-10-23 (32)/ Ongoing	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082101; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-23 (32)/ 2020-10-30 (39)	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Immune system disorders/ Drug hypersensitivity/ ALLERGIC REACTION TO METRONIDAZOLE	2020-11-12 (52)/ 2020-11-14 (54)	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3082105; Age (years): 73; Sex: M; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-09-18 (25)/ 2020-10-19 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082130; Age (years): 68; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Thermal burn/ BURN (RIGHT FOREARM)	2020-10-16 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082171; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Clostridium difficile colitis/ DIARRHEA DIAGNOSED WITH C. DIFF	2020-09-07 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3082178; Age (years): 87; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-29 (28)/ 2020-11-23 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082197; Age (years): 74; Sex: M; Race: WHITE							
Infections and infestations/ Clostridium difficile colitis/ DIARRHEA DIAGNOSED WITH C.DIFF	2020-10-07 (34)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082226; Age (years): 69; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Hypoaesthesia oral/ NUMBNESS OF LIPS AND TONGUE	2020-10-09 15:57 (1)/ 2020-10-11 08:00 (2)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Paraesthesia oral/ TINGLING OF LIPS	2020-10-09 15:57 (1)/ 2020-10-11 08:00 (2)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Paraesthesia oral/ TINGLING ON TIP OF TONGUE	2020-10-09 15:57 (1)/ 2020-10-11 08:00 (2)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3082236; Age (years): 56; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ SPIDER BITE [RIGHT UPPER CHEST]	2020-10-02 (19)/ 2020-10-16 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082236; Age (years): 56; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Splenomegaly/ ENLARGED SPLEEN [SPLENOMEGALY]	2020-11-02 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Abdominal hernia/ ABDOMINAL HERNIA	2020-11-02 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082245; Age (years): 80; Sex: F; Race: WHITE							
Infections and infestations/ Infected dermal cyst/ INFECTED SEBACEOUS CYST (LEFT AXILLA)	2020-10-22 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3082250; Age (years): 67; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Vertigo positional/ POSITIONAL VERTIGO	2020-10-25 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3082250; Age (years): 67; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Meniere's disease/ MENIERE'S DISEASE	2020-11-09 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3082257; Age (years): 72; Sex: F; Race: WHITE							
Eye disorders/ Glaucoma/ GLAUCOMA [BOTH EYES]	2020-11-02 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3092011; Age (years): 68; Sex: F; Race: WHITE							
Surgical and medical procedures/ Cataract operation/ RIGHT EYE CATARACT SURGERY	2020-09-10 (3)/ 2020-09-10 (3)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Eye disorders/ Cataract/ LEFT EYE CATARAT SURGERY	2020-09-14 (7)/ 2020-09-14 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092011; Age (years): 68; Sex: F; Race: WHITE							
Eye disorders/ Eye disorder/ EYE LENSE REPLACEMENT	2020-09-14 (7)/ 2020-09-14 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3092022; Age (years): 57; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ SECOND METATARSAL REPLACEMENT	2020-09-22 (21)/ 2020-09-22 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: ROD SURGICALLY PLACED IN FOOT.
Injury, poisoning and procedural complications/ Limb injury/ RIGHT TOE INJURY	2020-09-22 (21)/ 2020-09-22 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SECOND METATARSAL REPLACEMENT
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-03 (32)/ 2020-10-06 (35)	Yes/ Yes/ No	4	Yes/3 (2020-10-03/ 2020-10-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092029; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 SYMPTOMS	2020-11-07 (66)/ Ongoing	Yes/ Yes/ No	1	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3092086; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-08-16 (9)/ 2020-09-07 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3092091; Age (years): 78; Sex: M; Race: WHITE							
Nervous system disorders/ Transient ischaemic attack/ TRANSIENT ISCHEMIC ATTACK	2020-09-22 20:00 (14)/ 2020-09-22 (14)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPS	2020-10-22 (44)/ 2020-10-26 (48)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3092110; Age (years): 44; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHES	2020-09-14 (1)/ 2020-09-21 (8)	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-14 (1)/ 2020-09-22 (9)	Yes/ Yes/ Yes	1	No	R/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-15 (2)/ 2020-09-26 (13)	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3102008; Age (years): 62; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Upper limb fracture/ L SHOULDER FX	2020-09-28 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102020; Age (years): 68; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-23 (27)/	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3102028; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES RASH L SHOULDER	2020-08-23 (26)/ 2020-09-06 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3102061; Age (years): 72; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION WITH RVR	2020-08-20 (22)/ 2020-08-23 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-20 (22)/ 2020-08-23 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102061; Age (years): 72; Sex: M; Race: WHITE							
Vascular disorders/ Hypertensive urgency/ HYPERTENSIVE URGENCY	2020-08-20 (22)/ 2020-08-23 (25)	Yes/ Yes/ No	3	Yes/3 (2020-08-20/ 2020-08-23)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3102082; Age (years): 65; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-11-10 (75)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	2020-11-11 (76)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-11/ 2020-11-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3102085; Age (years): 68; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-05 (36)/ 2020-10-15 (46)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102085; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-05 (36)/ 2020-10-15 (46)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3102117; Age (years): 69; Sex: M; Race: WHITE							
Cardiac disorders/ Palpitations/ HEART PALPITATIONS	2020-09-26 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3102179; Age (years): 19; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ DRY COUGH	2020-08-29 (19)/ 2020-09-22 (43)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3102185; Age (years): 36; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain lower/ LOWER ABDOMINAL PAIN	2020-09-14 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102223; Age (years): 87; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-10-05 (22)/ 2020-10-10 (27)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3102229; Age (years): 26; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Tonsillitis/ TONSILLITIS	2020-10-09 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3102239; Age (years): 70; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ UPPER ABDOMINAL PAIN	2020-09-18 (3)/ 2020-09-29 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Hepatobiliary disorders/ Cholelithiasis/ CHOLELITHIASIS	2020-09-22 (7)/ 2020-09-26 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102239; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS OF ABDOMINAL WALL POST SURGICAL CHOLECYSTECTOMY	2020-09-28 (13)/ 2020-10-15 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3102281; Age (years): 37; Sex: F; Race: WHITE							
Infections and infestations/ Cystitis/ BLADDER INFECTION	2020-11-09 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3102284; Age (years): 44; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Productive cough/ EXCESSIVE PHLEGM	2020-09-24 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3102333; Age (years): 59; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ LEFT FOOT FRACTURE	2020-09-30 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102347; Age (years): 56; Sex: F; Race: MULTIPLE: (b) (6)							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GERD	2020-10-07 (26)/ Ongoing	Yes/ Yes/ No		No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3102415; Age (years): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Bone pain/ ACHES IN BONES	2020-10-20 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Muscle spasms/ CRAMPING KNEES AND BACK	2020-10-20 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Lethargy/ LETHARGY	2020-10-20 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3102415; Age (years): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 (13)/ 2020-10-22 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112005; Age (years): 58; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ TOOTH DECAY	2020-08-03 (6)/ 2020-09-17 (51)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3112036; Age (years): 29; Sex: M; Race: WHITE							
Infections and infestations/ Paronychia/ PARONYCHIA-LEFT 4TH FINGER	2020-09-18 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3112039; Age (years): 49; Sex: F; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Product issues/ Device breakage/ SPONTANEOUS RUPTURE OF LEFT BREAST IMPLANT	2020-08-13 (15)/ 2020-08-17 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3112046; Age (years): 45; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH LOWER BACK-NON-URTICARIAL	2020-08-28 20:00 (1)/ 2020-09-03 (7)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Constipation/ CONSTIPATED	2020-08-31 (4)/ 2020-09-04 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Limb discomfort/ LEFT LEG HEAVINESS	2020-08-31 (4)/ 2020-09-05 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112046; Age (years): 45; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Limb discomfort/ LEFT LEG HEAVINESS WITH NUMBNESS	2020-08-31 (4)/ 2020-09-05 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Sciatica/ LEFT LEG HEAVINESS WITH TINGLING (SCIATICA)	2020-08-31 (4)/ 2020-09-05 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ URI	2020-11-05 (70)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3112050; Age (years): 61; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-23 (57)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112065; Age (years): 76; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Rib fracture/ 2 RIGHT SIDE CRACKED RIBS	2020-09-15 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3112084; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-17 (79)/ 2020-11-21 (83)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112113; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	2020-08-19 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-16 (15)/ 2020-09-16 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112113; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ KNEE JOINT ASPIRATION DUE TO OSTEOARTHRITIS	2020-11-10 (70)/ 2020-11-10 (70)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3112120; Age (years): 37; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ POST PARTUM ANXIETY	2020-09-02 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112121; Age (years): 54; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant melanoma/ MELANOMA	2020-09-09 (8)/ 2020-09-21 (20)	Yes/ Yes/ No	4	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112121; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-03 (32)/ 2020-10-06 (35)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Postoperative wound infection/ SURGICAL SITE INFECTION	2020-10-21 (50)/ 2020-10-28 (57)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112122; Age (years): 45; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-18 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-08-18 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112128; Age (years): 30; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Abdominal pain lower/ RIGHT LOWER QUADRANT PAIN	2020-09-12 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112142; Age (years): 53; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ RIGHT EAR INFECTION	2020-09-25 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3112157; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-08-20 (14)/ 2020-08-25 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112201; Age (years): 36; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis/ NONSPECIFIC PHARYNGITIS	2020-11-10 (61)/ 2020-11-16 (67)	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112206; Age (years): 75; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS RIGHT LOWER EYELID	2020-11-18 (71)/ 2020-11-22 (75)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112254; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREPT THROAT	2020-09-18 (9)/ 2020-09-20 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112285; Age (years): 33; Sex: F; Race: WHITE							
Infections and infestations/ Injection site cellulitis/ POSSIBLE LEFT DELTOID CELLULITIS AT INJECTION SITE	2020-08-25 (9)/ 2020-09-04 (19)	Yes/ Yes/ No	2	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112297; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-09-16 10:30 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3112312; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-11-01 (48)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN
Subject ID: US3112317; Age (years): 18; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING OF ANXIETY	2020-09-01 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-09-01 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112341; Age (years): 45; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-23 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3112360; Age (years): 43; Sex: F; Race: WHITE							
Nervous system disorders/ Hyperaesthesia/ TACTILE HYPERESTHESIA	2020-09-21 19:01 (1)/ 2020-09-22 23:00 (2)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3112364; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-27 (37)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3112376; Age (years): 38; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Joint swelling/ RIGHT ANKLE SWELLING	2020-10-15 (24)/ 2020-10-17 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3112389; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-11-10 (49)/ 2020-11-15 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3112465; Age (years): 39; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-22 (13)/ 2020-10-06 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122001; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES - NECK AND LEFT SHOULDER	2020-09-06 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122010; Age (years): 62; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Lung cancer metastatic/ RECURRENCE OF THROAT CANCER WITH METASTASES TO LUNGS	2020-08-12 (17)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3122034; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Vessel puncture site haematoma/ HEMATOMA AT VENIPUNCTURE SITE	2020-09-02 (9)/ 2020-09-11 (18)	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3122047; Age (years): 28; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ HYPERSENSITIVITY RASH - BILATERAL ELBOWS (MACULAR - URTICARIAL)	2020-08-04 (9)/ 2020-08-11 (16)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3122089; Age (years): 47; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA (WITHOUT FEVER)	2020-09-04 (11)/ 2020-09-12 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3122151; Age (years): 41; Sex: M; Race: WHITE							
Infections and infestations/ Lyme disease/ LYME DISEASE	2020-10-19 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-19 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3132011; Age (years): 71; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Salivary gland calculus/ SALIVARY GLAND STONE LEFT	2020-09-28 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3132037; Age (years): 54; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-08 (40)/ Ongoing	Yes/ Yes/ No		Yes/3 (2020-11-14/)		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-08 (40)/ Ongoing	Yes/ Yes/ No		Yes/3 (2020-11-14/)		DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	UNKNOWN
Vascular disorders/ Peripheral coldness/ COLD HANDS AND FEET	2020-11-08 (40)/ Ongoing	Yes/ Yes/ No		3 (2020-11-14/)		DOSE NOT CHANGED/ NONE	UNKNOWN

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3142041; Age (years): 59; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSIVE EPISODE	2020-08-27 08:08 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3142185; Age (years): 73; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Volvulus/ INTESTINAL TORSION	2020-09-18 (3)/ 2020-09-26 (11)	Yes/ Yes/ No	3	Yes/3 (2020-09-18/ 2020-09-26)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3142268; Age (years): 60; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCER	2020-10-22 (23)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-22/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152001; Age (years): 73; Sex: M; Race: WHITE							
Vascular disorders/ Raynaud's phenomenon/ RAUNAUD'S DISEASE	2020-10-30 (59)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152009; Age (years): 25; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Undifferentiated connective tissue disease/ UNDIFFERENTIATED CONNECTIVE TISSUE DISEASE	2020-08-14 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE, CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152018; Age (years): 45; Sex: F; Race: OTHER: (b) (6)							
Psychiatric disorders/ Insomnia/ WORSENING INSOMNIA	2020-10-19 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152023; Age (years): 40; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Breast disorder/ UNSPECIFIED ABNORMALITY LEFT BREAST	2020-09-14 (14)/ 2020-10-07 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152026; Age (years): 67; Sex: F; Race: WHITE							
Product issues/ Device breakage/ RIGHT RUPTURED BREAST IMPLANT	2020-08-14 (17)/ 2020-08-24 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Investigations/ White blood cell count increased/ ELEVATED WHITE CELL COUNT	2020-10-08 (38)/ 2020-11-09 (70)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152032; Age (years): 70; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ WORSENING OF GASTROESOPHAGEAL REFLUX DISEASE	2020-08-18 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3152052; Age (years): 24; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-08-21 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Joint injury/ SCRAPED RIGHT KNEE	2020-10-17 (52)/ 2020-10-19 (54)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152059; Age (years): 33; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION- LEFT UPPER ARM	2020-09-06 (10)/ 2020-09-13 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Granuloma/ GRANULOMA- LEFT TRICEP	2020-09-22 (26)/ 2020-10-14 (48)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3152066; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-05 (51)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152076; Age (years): 64; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ TENDONITIS LEFT FOOT	2020-10-06 (29)/ 2020-10-20 (43)	Yes/ Yes/ No	2	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152081; Age (years): 46; Sex: M; Race: MULTIPLE: (b) (6)							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-23 (52)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152087; Age (years): 28; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ HERNIATED DISC C5-C6	2020-08-07 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3152087; Age (years): 28; Sex: M; Race: WHITE							
Infections and infestations/ Chlamydial infection/ CHLAMYDIA INFECTION	2020-09-15 (14)/ 2020-09-18 (17)	Yes/ Yes/ No	2	No	NA/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Corneal abrasion/ BILATERAL CORNEAL ABRASION	2020-11-12 (72)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Eye disorders/ Vision blurred/ BLURRY VISION OF LEFT EYE	2020-11-16 (76)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152092; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-19 (42)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152106; Age (years): 55; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ CRACKED LEFT SECOND UPPER MOLAR	2020-08-14 (9)/ 2020-09-01 (27)	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3152113; Age (years): 28; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Gonorrhoea/ POSSIBLE GONORRHEA EXPOSURE	2020-09-07 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3152129; Age (years): 52; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ CRACKED FILLING, TOOTH #32	2020-09-03 (25)/ 2020-09-04 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3152141; Age (years): 39; Sex: M; Race: WHITE							
Eye disorders/ Eyelid cyst/ BENIGN LEFT UPPER LID EYE LID CYST	2020-09-03 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152141; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Hordeolum/ STYE RIGHT EYE	2020-10-28 (50)/ 2020-11-03 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152147; Age (years): 46; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Meniscus injury/ LEFT TORN MENISCUS	2020-10-14 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Meniscus injury/ RIGHT TORN MENISCUS	2020-10-29 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152176; Age (years): 30; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ RECTUS ABDOMINUS MUSCLE STRAIN	2020-09-15 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152192; Age (years): 34; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-26 (13)/ 2020-08-28 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152200; Age (years): 70; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-08-14 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152204; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Toothache/ PAIN RIGHT LOWER WISDOM TOOTH	2020-09-22 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152214; Age (years): 72; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT INGUINAL LYMPHADENOPATHY	2020-09-16 14:17 (33)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Supraventricular extrasystoles/ PREMATURE ATRIAL CONTRACTIONS	2020-10-28 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152218; Age (years): 57; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety disorder/ WORSENING ANXIETY DISORDER	2020-09-29 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-09-29 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152231; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoporosis/ OSTEOPOROSIS	2020-09-11 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Tooth infection/ DENTAL INFECTION	2020-10-01 17:00 (2)/ 2020-10-05 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152272; Age (years): 52; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Food poisoning/ POISON SUMAC	2020-10-02 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152273; Age (years): 48; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 INFECTION	2020-10-12 (27)/ 2020-10-20 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152281; Age (years): 53; Sex: M; Race: WHITE							
Nervous system disorders/ Sciatica/ SCIATICA LEFT-SIDED	2020-10-24 (40)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Pyelonephritis/ PYELONEPHRITIS	2020-10-25 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3152286; Age (years): 63; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament injury/ RIGHT KNEE MCL INJURY UNSPECIFIED	2020-10-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Meniscus injury/ MENISCUS TEAR RIGHT KNEE	2020-10-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152292; Age (years): 23; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ SPRAINED ANKLE	2020-09-28 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3152294; Age (years): 36; Sex: F; Race: WHITE							
Psychiatric disorders/ Post-traumatic stress disorder/ POST TRAUMATIC STRESS DISORDER	2020-09-29 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152321; Age (years): 28; Sex: M; Race: MULTIPLE: (b) (6)							
Injury, poisoning and procedural complications/ Fall/ FALL DOWNSTAIRS	2020-08-25 (6)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-08-25 (6)/ 2020-08-30 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152332; Age (years): 28; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ WORSENING OF ACNE	2020-10-07 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152336; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-21 00:00 (1)/ 2020-08-26 00:00 (6)	No/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152342; Age (years): 68; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ LEFT KIDNEY STONE 4MM	2020-10-07 (15)/ 2020-10-10 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152350; Age (years): 46; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-28 (8)/ 2020-08-30 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152351; Age (years): 57; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL CARCINOMA	2020-11-13 (50)/ 2020-11-13 (50)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3152363; Age (years): 50; Sex: F; Race: ASIAN							
Immune system disorders/ Immune system disorder/ ABNORMAL AUTOIMMUNE MARKERS	2020-10-26 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152375; Age (years): 44; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis atopic/ WORSENING OF ATOPIC DERMATITIS	2020-10-01 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152377; Age (years): 22; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Peripheral swelling/ BILATERAL LEG SWELLING	2020-09-22 00:00 (1)/ 2020-09-22 00:01 (1)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Fibrin D dimer increased/ ELEVATED D-DIMER	2020-09-22 00:00 (1)/ 2020-09-22 00:01 (1)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ BILATERAL LEG PAIN	2020-09-22 00:00 (1)/ 2020-09-27 00:00 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3152384; Age (years): 58; Sex: M; Race: ASIAN							
Gastrointestinal disorders/ Dental caries/ CAVITY TOOTH #14	2020-09-28 (6)/ 2020-11-17 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152397; Age (years): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-25 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152403; Age (years): 54; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-03 (25)/ 2020-10-10 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Ear pain/ LEFT EAR OTALGIA	2020-10-05 (27)/ 2020-10-11 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Otitis media/ LEFT EAR MEDIA OTITIS	2020-10-10 (32)/ 2020-10-11 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152413; Age (years): 48; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-19 (21)/ 2020-10-25 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152418; Age (years): 45; Sex: M; Race: ASIAN							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-10 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152424; Age (years): 63; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Tendonitis/ LEFT SHOULDER TENDONITIS	2020-10-14 (14)/ 2020-10-18 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152430; Age (years): 25; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING LEFT SHOULDER PAIN	2020-10-04 (3)/ 2020-10-15 (14)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152430; Age (years): 25; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ WORSENING NECK PAIN	2020-10-04 (3)/ 2020-10-15 (14)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152434; Age (years): 58; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection bacterial/ BACTERIAL URINARY TRACT INFECTION	2020-11-23 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152437; Age (years): 57; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-12 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152437; Age (years): 57; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Upper-airway cough syndrome/ POSTNASAL DRIP	2020-10-12 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152447; Age (years): 34; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Paronychia/ PARONYCHIA	2020-10-15 (9)/ 2020-10-21 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3152454; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Nodule/ SMALL BENIGN NODULE	2020-10-28 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152459; Age (years): 41; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash vesicular/ HERPETIC RASH GROIN	2020-10-27 (20)/ 2020-11-15 (39)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152479; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-09 (27)/ 2020-11-16 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Depression/ DEPRESSION	2020-11-12 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3152537; Age (years): 62; Sex: M; Race: OTHER: (b) (6)							
Reproductive system and breast disorders/ Prostatitis/ PROSTATITIS	2020-11-12 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3152545; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN POST AURICULAR LYMPH NODE ON RIGHT SIDE	2020-11-05 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3152545; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-06 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162003; Age (years): 75; Sex: F; Race: WHITE							
Hepatobiliary disorders/ Cholecystitis acute/ ACUTE CHOLECYSTITIS	2020-08-27 (4)/ 2020-08-27 (4)	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Cardiac disorders/ Acute myocardial infarction/ ACUTE MYOCARDIAL INFARCTION	2020-09-07 (15)/ 2020-09-08 (16)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-08/ 2020-09-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162003; Age (years): 75; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA DUE TO ACUTE MYOCARDIAL INFARCTION	2020-09-08 (16)/ 2020-09-08 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-09-09 (17)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH SECONDARY TO CARVEDILOL	2020-09-11 (19)/ 2020-09-22 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162007; Age (years): 68; Sex: F; Race: WHITE							
Nervous system disorders/ Amnesia/ MEMORY LOSS	2020-07-29 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Cerebrovascular accident/ MILD CEREBROVASCULAR ACCIDENT	2020-07-30 (4)/ 2020-07-31 (5)	Yes/ Yes/ No	3	Yes/3 (2020-07-30/ 2020-07-31)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ OCCIPITAL HEADACHE	2020-07-30 (4)/ 2020-08-01 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162017; Age (years): 33; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Tonsillitis/ RIGHT TONSILLITIS	2020-09-11 20:00 (17)/ 2020-09-15 08:00 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162032; Age (years): 26; Sex: F; Race: MULTIPLE: (b) (6)							
Injury, poisoning and procedural complications/ Arthropod bite/ INSECT BITE	2020-09-10 (15)/ 2020-09-14 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162033; Age (years): 34; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-09-16 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162048; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Vulvovaginal candidiasis/ CANDIDA VAGINITIS	2020-08-14 (12)/ 2020-09-24 (53)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-03 (34)/ 2020-10-13 (44)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162049; Age (years): 71; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Injury, poisoning and procedural complications/ Procedural pain/ PAIN FROM DENTAL PROCEDURE	2020-09-03 (4)/ 2020-09-06 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162052; Age (years): 39; Sex: F; Race: WHITE							
Psychiatric disorders/ Bipolar disorder/ WORSENING OF BIPOLAR DISORDER	2020-08-11 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-22 (19)/ 2020-08-27 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Folliculitis/ LEFT INGUINAL FOLLICULITIS	2020-09-01 07:00 (28)/ 2020-10-09 (67)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162052; Age (years): 39; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ LEFT ANKLE SPRAIN	2020-09-12 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162056; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ FRONTAL SINUSITIS	2020-08-07 (4)/ 2020-08-13 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162078; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-14 (8)/ 2020-09-03 (28)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162082; Age (years): 71; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ LEFT LOWER MOLAR TOOTH FRACTURE	2020-10-26 (53)/ 2020-10-26 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162093; Age (years): 29; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	2020-09-20 (13)/ 2020-10-04 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162104; Age (years): 31; Sex: M; Race: ASIAN							
Injury, poisoning and procedural complications/ Concussion/ POST CONCUSSION HEADACHE	2020-08-13 06:30 (1)/ 2020-08-17 06:30 (5)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162114; Age (years): 29; Sex: F; Race: WHITE							
Nervous system disorders/ Anosmia/ LOSS OF SMELL	2020-10-07 (28)/ 2020-10-21 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162117; Age (years): 26; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-08-28 (16)/ 2020-09-06 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162123; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ ACUTE VIRAL INFECTION, UNSPECIFIED	2020-11-10 (56)/ 2020-11-14 (60)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162129; Age (years): 34; Sex: M; Race: WHITE							
Nervous system disorders/ Primary headache associated with sexual activity/ INTERMITTENT SEVERE OCCIDENTAL HEADACHE PRECIPITATED BY INTERCOURSE	2020-08-22 (9)/ 2020-08-26 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-31 (48)/ 2020-11-05 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162142; Age (years): 79; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ LEFT LUMBAR PAIN	2020-09-29 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162151; Age (years): 21; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-01 (45)/ 2020-11-05 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162161; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-07 (21)/ 2020-10-15 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162168; Age (years): 53; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Vertigo positional/ WORSENING OF BENIGN POSITIONAL VERTIGO	2020-08-24 (4)/ 2020-08-26 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162171; Age (years): 39; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-16 (61)/ 2020-11-21 (66)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162181; Age (years): 77; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-22 (31)/ 2020-11-01 (41)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162182; Age (years): 69; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ WORSENING (INCREASE) OF SYSTOLIC BLOOD PRESSURE	2020-08-25 15:23 (1)/ 2020-08-28 (4)	No/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162182; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-23 (2)/ 2020-10-03 (12)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162183; Age (years): 82; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDER PAIN	2020-10-20 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162184; Age (years): 72; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	2020-09-17 (24)/ 2020-10-05 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT SHOULDER SPRAIN	2020-09-22 18:00 (1)/ 2020-10-01 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162218; Age (years): 20; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-25 (25)/ 2020-11-23 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162223; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-10 (40)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162230; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-25 (19)/ 2020-10-29 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3162233; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ INTERMITTENT FATIGUE	2020-09-13 (4)/ 2020-09-24 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3162250; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-10-07 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3162286; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-03 (19)/ 2020-11-17 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3162290; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Viral infection/ VIRAL INFECTION, UNSPECIFIED	2020-10-26 (8)/ 2020-11-05 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172012; Age (years): 52; Sex: M; Race: WHITE							
Investigations/ Hepatic enzyme abnormal/ ABNORMAL LIVER ENZYMES	2020-08-17 (8)/ 2020-10-23 (75)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Blood cholesterol increased/ ABNORMAL HIGH CHOLESTEROL	2020-09-28 (18)/ 2020-10-23 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Blood triglycerides increased/ ABNORMAL HIGH TRIGLYCERIDES	2020-09-28 (18)/ 2020-10-23 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172050; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE LEFT DELTOID AREA ERYTHEMA (MACULOPAPULAR NON-URTICARIAL)	2020-08-19 (9)/ 2020-08-22 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site induration/ INDURATION LEFT DELTOID AREA AT INJECTION SITE	2020-08-19 (9)/ 2020-08-22 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172050; Age (years): 45; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ MILD INJECTION SITE PAIN LEFT DELTOID AREA	2020-08-19 (9)/ 2020-08-22 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site swelling/ INJECTION SITE SWELLING LEFT DELTOID AREA	2020-08-19 (9)/ 2020-08-22 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Migraine/ MIGRAINE EXACERBATION	2020-09-27 (20)/ 2020-09-27 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172059; Age (years): 57; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION OF NEW ONSET	2020-08-12 12:18 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172112; Age (years): 62; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ WORSENING NEPHROLITHIASIS RIGHT KIDNEY CALCULI	2020-10-31 (79)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172149; Age (years): 38; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT ANKLE SPRAIN	2020-09-21 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172159; Age (years): 66; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Lipoma/ BENIGN LIPOMA	2020-09-30 (17)/ 2020-09-30 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3172275; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-12 (23)/ 2020-09-15 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-11-06 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172284; Age (years): 61; Sex: M; Race: WHITE							
Investigations/ Haemoglobin decreased/ DECREASED HEMOGLOBIN	2020-10-27 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172330; Age (years): 63; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-10-12 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172333; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Salpingitis/ BILATERAL ACUTE SALPINGITIS	2020-11-09 (47)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-09/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172342; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-02 (41)/ 2020-11-11 (50)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172371; Age (years): 68; Sex: F; Race: WHITE							
Nervous system disorders/ Carpal tunnel syndrome/ WORSENING OF BASELINE CARPAL TUNNEL SYNDROME	2020-09-18 (23)/ 2020-10-11 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3172382; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	2020-10-23 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3172408; Age (years): 70; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bursitis/ ACUTE EXACERBATION OF CHRONIC BURSITIS RIGHT SHOULDER	2020-11-17 19:00 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3172419; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Neck pain/ ACUTE EXACERBATION OF CHRONIC CERVICALGIA	2020-11-16 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3172469; Age (years): 59; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ WORSENING OF BASELINE LEFT THIGH PAIN	2020-11-14 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3182002; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-09-14 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3182095; Age (years): 61; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-03 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3182100; Age (years): 55; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS LEFT FOOT AND ANKLE	2020-08-01 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3182149; Age (years): 70; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant melanoma/ MELANOMA LEFT LOWER BACK	2020-09-29 (29)/ 2020-09-29 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3182194; Age (years): 54; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Hidradenitis/ EXACERBATION OF HYDRADENITIS	2020-08-23 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3182199; Age (years): 65; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ EXACERBATION OF ANXIETY	2020-09-02 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3182203; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-11-11 (69)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3182289; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ BILATERAL EAR INFECTION	2020-09-02 (23)/ 2020-09-09 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192006; Age (years): 69; Sex: M; Race: WHITE							
Vascular disorders/ Hypotension/ HYPOTENSION	2020-08-16 (16)/ 2020-08-17 (17)	Yes/ Yes/ No	4	Yes/3 (2020-08-16/ 2020-08-17)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192192; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION FROM THE FALL	2020-10-02 (23)/ 2020-10-02 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Fall/ FALL FROM A SECOND FLOOR TO FIRST FLOOR	2020-10-02 (23)/ 2020-10-02 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3192345; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Pyelonephritis acute/ ACUTE PYELONEPHRITIS	2020-08-27 (5)/ 2020-09-04 (13)	Yes/ Yes/ No	4	Yes/3 (2020-08-28/ 2020-09-02)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192345; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Urosepsis/ UROSEPSIS	2020-08-27 (5)/ 2020-09-04 (13)	Yes/ Yes/ No	4	Yes/3 (2020-08-28/ 2020-09-02)	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192363; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Abscess limb/ INGROWN HAIR ABSCESS INNER THIGH	2020-08-27 (2)/ 2020-09-01 09:00 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192486; Age (years): 73; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ DEEP VEIN THROMBOSIS & PULMONARY EMBOLISM	2020-11-02 (41)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192486; Age (years): 73; Sex: M; Race: WHITE							
Surgical and medical procedures/ Pancreatic stent placement/ STENT PLACEMENT PANCREAS	2020-11-02 (41)/ 2020-11-02 (41)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Surgical and medical procedures/ Transfusion/ BLOOD TRANSFUSION	2020-11-02 (41)/ 2020-11-04 (43)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED WITH SEQUELAE: COLONOSCOPY
Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GI BLEED	2020-11-02 (41)/ 2020-11-08 (47)	Yes/ Yes/ No	3	Yes/3 (2020-11-02/ 2020-11-08)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED WITH SEQUELAE: COLONOSCOPY
Subject ID: US3192506; Age (years): 73; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL KNEE PAIN	2020-08-26 20:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NA	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3192551; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-18 (22)/ 2020-10-06 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3192552; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ BILATERAL ARM CELLULITIS	2020-09-24 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3192813; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Muscle strain/ BACK STRAIN	2020-10-31 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202014; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Staphylococcal infection/ STAPH INFECTION ON BILATERAL HANDS AND ARMS	2020-09-01 (28)/ 2020-09-15 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202015; Age (years): 49; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Cartilage injury/ TORN RIGHT LABRUM	2020-09-01 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Muscle rupture/ TORN RIGHT BICEP	2020-09-01 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ TORN RIGHT ROTATOR CUFF	2020-09-01 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202020; Age (years): 57; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma of skin/ SKIN CANCER-SQUAMOUS CELL RT ARM	2020-10-06 (35)/ 2020-10-26 (55)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Wound/ POST EXCISIONAL WOUND	2020-10-26 (55)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3202023; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Gastroenteritis viral/ VIRAL GASTROENTERITIS	2020-10-28 (51)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202023; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Infected bite/ INFECTED CAT BITE WOUND	2020-11-05 (59)/ 2020-11-12 (66)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202053; Age (years): 72; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-18 (12)/ 2020-08-21 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202054; Age (years): 36; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-17 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-17 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202054; Age (years): 36; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-09-17 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202067; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Folliculitis/ FOLICULITIS	2020-09-23 (13)/ 2020-09-25 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202068; Age (years): 73; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Oral mucosal blistering/ BLISTERS IN MOUTH	2020-10-21 (44)/ 2020-10-23 (46)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3202086; Age (years): 56; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-09-22 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202086; Age (years): 56; Sex: M; Race: WHITE							
Infections and infestations/ Rhinitis/ INFECTIVE RHINITIS	2020-09-22 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-09-22 (15)/ 2020-09-25 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-22 (15)/ 2020-09-26 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-22 (15)/ 2020-09-26 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202086; Age (years): 56; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-22 (15)/ 2020-10-05 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3202091; Age (years): 60; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS, 9 DAYS POST VACCINATION	2020-08-09 (1)/ 2020-09-01 (24)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3202120; Age (years): 39; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-01 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202120; Age (years): 39; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-01 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3202156; Age (years): 34; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-18 (32)/ 2020-11-02 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202161; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION OF UNKNOWN ETIOLOGY	2020-10-18 (38)/ 2020-10-22 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202162; Age (years): 66; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HIGH BLOOD PRESSURE	2020-11-03 (54)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202191; Age (years): 77; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION OF RIGHT ELBOW	2020-10-08 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202191; Age (years): 77; Sex: M; Race: WHITE							
Infections and infestations/ Wound infection/ RIGHT ELBOW WOUND INFECTION	2020-10-27 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3202200; Age (years): 46; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-05 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3202231; Age (years): 77; Sex: F; Race: WHITE							
Nervous system disorders/ Embolic stroke/ EMBOLIC STROKE	2020-10-31 (48)/ 2020-10-31 (48)	Yes/ Yes/ No	2	Yes/3 (2020-10-31/ 2020-11-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202260; Age (years): 64; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEG CRAMPS	2020-10-12 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202264; Age (years): 53; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABSCESSED TOOTH	2020-09-05 (18)/ 2020-09-08 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202294; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-11-04 (49)/ 2020-11-07 (52)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202297; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-09-28 (8)/ 2020-10-05 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202297; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS/ENTEROVIRUS INFECTION	2020-11-12 (53)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202310; Age (years): 63; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Hiatus hernia/ WORSENING OF HIATAL HERNIA	2020-10-06 (14)/ 2020-10-24 (32)	Yes/ Yes/ No	2	Yes/3 (2020-10-23/ 2020-10-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3202343; Age (years): 24; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST WALL PAIN	2020-10-11 (24)/ 2020-10-15 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202343; Age (years): 24; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-11 (24)/ 2020-10-15 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-10-12 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3202366; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Vulvovaginal candidiasis/ VAGINAL CANDIDIASIS	2020-09-02 (3)/ 2020-09-03 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-02 (3)/ 2020-09-08 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202375; Age (years): 56; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-28 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-28 (28)/ 2020-09-28 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-28 (28)/ 2020-09-29 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-28 (28)/ 2020-09-29 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202375; Age (years): 56; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-28 (28)/ 2020-09-29 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-28 (28)/ 2020-09-29 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-30 (30)/ 2020-09-30 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202375; Age (years): 56; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-30 (30)/ 2020-10-01 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3202388; Age (years): 48; Sex: F; Race: WHITE							
Nervous system disorders/ Nerve compression/ MUSCLE SPASMS-PINCHED NERVE	2020-10-27 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3202391; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION OF UNKNOWN CAUSE	2020-10-15 (15)/ 2020-10-17 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3202397; Age (years): 38; Sex: M; Race: WHITE							
Infections and infestations/ Localised infection/ TOE INFECTION	2020-09-30 (27)/ 2020-10-13 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3202399; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Viral upper respiratory tract infection/ URI- PROBABLY VIRAL	2020-09-23 (20)/ 2020-10-01 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212002; Age (years): 67; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-09 (40)/ 2020-10-14 (45)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212013; Age (years): 45; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Uterine haemorrhage/ ABNORMAL UTERINE BLEEDING	2020-08-27 (25)/ 2020-08-28 (26)	Yes/ Yes/ No	3	Yes/3 (2020-08-27/ 2020-08-28)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-12 (6)/ 2020-10-19 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Plantar fasciitis/ RIGHT FOOT PAIN (PLANTAR FASCIITIS)	2020-10-22 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212016; Age (years): 49; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-10 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212026; Age (years): 36; Sex: F; Race: ASIAN							
Infections and infestations/ Tooth abscess/ ROOT CANAL ABSCESS	2020-08-24 (21)/ 2020-08-31 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3212028; Age (years): 67; Sex: M; Race: WHITE							
Cardiac disorders/ Acute coronary syndrome/ ACUTE CORONARY SYNDROME (NON ST ELEVATED MYOCARDIAL INFARCTION)	2020-10-20 (50)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-23/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212028; Age (years): 67; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-10-28 (58)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Metabolism and nutrition disorders/ Hypercholesterolaemia/ WORSENING OF HYPERCHOLESTEROLEMIA	2020-10-29 (59)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-29 (59)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212039; Age (years): 55; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE	2020-08-24 (21)/ 2020-09-04 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212079; Age (years): 72; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Cerumen impaction/ CERUMEN IMPACTION BILATERAL EARS	2020-08-12 (7)/ 2020-08-17 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3212083; Age (years): 68; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-08-20 (14)/ 2020-08-20 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212083; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Oedema peripheral/ EDEMA, RIGHT ANKLE	2020-08-20 (14)/ 2020-09-11 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ TENDERNESS, RIGHT ANKLE	2020-08-20 (14)/ 2020-09-11 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212085; Age (years): 25; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ SPRAINED RIGHT ANKLE	2020-09-02 (27)/ 2020-09-04 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212105; Age (years): 74; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Postmenopausal haemorrhage/ POSTMENOPAUSAL BLEEDING	2020-11-08 (56)/ 2020-11-15 (63)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212113; Age (years): 33; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Meniscus injury/ RIGHT KNEE PAIN/MENISCUS TEAR	2020-09-01 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3212123; Age (years): 53; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ DEPRESSION	2020-08-25 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Investigations/ Thyroid function test abnormal/ ABNORMAL THYROID LABS	2020-09-30 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3212125; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-09-24 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212126; Age (years): 69; Sex: M; Race: WHITE							
Eye disorders/ Vitreous disorder/ LEFT EYE VITREOUS FLUID LEAK	2020-08-20 (10)/ 2020-08-20 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3212131; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-10 11:00 (1)/ 2020-09-14 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212142; Age (years): 41; Sex: M; Race: WHITE							
Infections and infestations/ Wound infection/ INFECTION (CUT ON RIGHT HAND)	2020-08-23 (12)/ 2020-09-05 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212145; Age (years): 63; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermal cyst/ SEBACEOUS CYST (LEFT BUTTOCKS)	2020-08-25 (14)/ 2020-09-05 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ RIGHT ARM MUSCLE SORENESS	2020-09-01 (21)/ 2020-09-30 (50)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212159; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ DENTAL INFECTION (BOTTOM RIGHT GUM)	2020-09-18 10:09 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212173; Age (years): 71; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Neurodermatitis/ PRURIGO NODULARIS OF THE BILATERAL UPPER ARMS	2020-10-12 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3212182; Age (years): 20; Sex: F; Race: NOT REPORTED							
Infections and infestations/ Streptococcal infection/ GROUP B STREPTOCOCCAL INFECTION (GBS POSITIVE)	2020-10-15 (63)/ 2020-10-25 (73)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Pregnancy, puerperium and perinatal conditions/ Hyperemesis gravidarum/ HYPEREMESIS GRAVIDARUM	2020-10-26 (74)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3212199; Age (years): 38; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Blood blister/ BLOOD BLISTER, RIGHT FOOT	2020-10-20 (35)/ 2020-11-04 (50)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212204; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Eczema/ FACIAL ECZEMA EXACERBATION	2020-08-31 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Seborrhoeic dermatitis/ SEBORRHEIC DERMATITIS EXACERBATION OF THE SCALP	2020-08-31 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212206; Age (years): 58; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-11-12 (60)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212223; Age (years): 73; Sex: F; Race: WHITE							
Renal and urinary disorders/ Bladder prolapse/ BLADDER PROLAPSE	2020-10-28 (45)/ 2020-11-05 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3212226; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-10-29 (43)/ 2020-11-12 (57)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212252; Age (years): 64; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ACUTE WORSENING OF CHRONIC LEFT HIP PAIN	2020-09-20 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212253; Age (years): 46; Sex: M; Race: ASIAN							
Metabolism and nutrition disorders/ Hyperlipidaemia/ WORSENING OF HYPERLIPIDEMIA	2020-09-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212260; Age (years): 55; Sex: F; Race: WHITE							
Eye disorders/ Noninfective conjunctivitis/ CONTACT LENS-INDUCED PAPILLARY CONJUNCTIVITIS, LEFT EYE	2020-08-27 (8)/ 2020-09-17 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3212264; Age (years): 39; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Melanocytic naevus/ ATYPICAL NEVUS - RIGHT BUTTOCK	2020-10-16 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3212265; Age (years): 62; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-04 (16)/ 2020-09-07 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212283; Age (years): 57; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis bacterial/ BACTERIAL SINUSITIS	2020-10-22 (32)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3212294; Age (years): 53; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 (3)/ 2020-09-01 (8)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis/ SINUSITIS	2020-08-30 (6)/ 2020-09-01 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Eye disorders/ Xerophthalmia/ XEROPHTHALMIA BILATERAL	2020-08-30 (6)/ 2020-09-02 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212296; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-27 (30)/ 2020-11-05 (39)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212299; Age (years): 56; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Deafness neurosensory/ ACUTE HIGH FREQUENCY HEARING LOSS, SENSORINEURAL, LEFT SIDE	2020-10-08 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Ear and labyrinth disorders/ Tinnitus/ TINNITUS, LEFT EAR	2020-10-08 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212326; Age (years): 46; Sex: F; Race: ASIAN							
Nervous system disorders/ Autonomic nervous system imbalance/ AUTONOMIC DYSFUNCTION	2020-10-18 (24)/ Ongoing	Yes/ Yes/ No	2	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212326; Age (years): 46; Sex: F; Race: ASIAN							
Infections and infestations/ Sinusitis/ ACUTE NON-RECURRENT PANSINUSITIS	2020-10-23 (29)/ 2020-11-02 (39)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Upper-airway cough syndrome/ POST-NASAL DRIP	2020-10-25 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212336; Age (years): 45; Sex: M; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-09-29 06:45 (1)/ 2020-09-30 (3)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3212350; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-10-16 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212354; Age (years): 44; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ HERNIATED DISKS IN SPINE	2020-09-18 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212375; Age (years): 53; Sex: F; Race: OTHER: (b) (6)							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ TYPE II DIABETES MELLITUS	2020-09-18 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212380; Age (years): 47; Sex: M; Race: WHITE							
Infections and infestations/ Hordeolum/ EXTERNAL HORDEOLUM RIGHT LOWER EYELID	2020-10-05 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3212394; Age (years): 62; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Otitis media/ OTITIS MEDIA IN RIGHT EAR	2020-11-02 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3212409; Age (years): 53; Sex: F; Race: WHITE							
Social circumstances/ Menopause/ MENOPAUSE	2020-10-27 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222004; Age (years): 69; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ UNCONTROLLED HYPERTENSION	2020-10-01 (22)/ 2020-10-02 (23)	Yes/ Yes/ No	4	Yes/3 (2020-10-01/ 2020-10-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222013; Age (years): 68; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-11-14 (72)/ 2020-11-16 (74)	Yes/ Yes/ No	3	Yes/3 (2020-11-14/ 2020-11-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3222054; Age (years): 54; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE/ARM REDNESS	2020-08-21 (14)/ 2020-08-26 (19)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222061; Age (years): 71; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Breast mass/ MASS ON RIGHT BREAST POSSITIVE FOR CANCER	2020-09-04 (26)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222063; Age (years): 68; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ UNCONTROLLED HYPERTENSION	2020-10-14 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-11 (62)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3222077; Age (years): 73; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2020-09-15 (7)/ 2020-10-02 (24)	Yes/ Yes/ No	4	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-22 (14)/ 2020-09-23 (15)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222091; Age (years): 59; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-09-10 (31)/ 2020-09-22 (43)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222095; Age (years): 71; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Corneal abrasion/ LEFT EYE CORNEA ABRASION	2020-09-10 (31)/ 2020-09-14 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3222117; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ POSITIVE COVID-19 RESULT FROM PCR.	2020-11-13 (65)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3222154; Age (years): 53; Sex: M; Race: WHITE							
Cardiac disorders/ Ventricular tachycardia/ VENTRICULAR TACHYCARIA	2020-10-23 (40)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222221; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Cellulitis/ ACUTE CELLULITIS LEFT LOWER EXTREMITY	2020-08-26 (8)/ 2020-11-12 (86)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222225; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Ear infection/ BILATERAL EAR INFECTION	2020-11-09 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222227; Age (years): 41; Sex: M; Race: WHITE							
Endocrine disorders/ Hypothyroidism/ HYPOTHYROIDISM	2020-10-23 (38)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3222291; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-09-29 (9)/ 2020-10-11 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-09-29 (9)/ 2020-10-11 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222296; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-23 00:00 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222299; Age (years): 57; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2020-10-03 (11)/ 2020-10-05 (13)	Yes/ Yes/ No	3	Yes/3 (2020-10-03/ 2020-10-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222316; Age (years): 79; Sex: M; Race: WHITE							
Immune system disorders/ Type IV hypersensitivity reaction/ DELAYED TYPE-HYPERSENSITIVITY	2020-08-31 (8)/ 2020-09-04 (12)	Yes/ Yes/ Yes	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222320; Age (years): 27; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rosacea/ ROSACEA	2020-08-27 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Skin infection/ SKIN INFECTION-LOWER STOMACH (FROM WAXING)	2020-10-07 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222323; Age (years): 75; Sex: M; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-11-16 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3222371; Age (years): 53; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-10-12 (18)/ 2020-10-24 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222373; Age (years): 70; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-09-19 (23)/ 2020-09-19 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222379; Age (years): 68; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Chronic myelomonocytic leukaemia/ CHRONIC MYELOMONOCYTIC LEUKEMIA	2020-09-23 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222380; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Joint injury/ L KNEE INJURY	2020-09-28 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Muscle strain/ L ANKLE STRAIN	2020-09-28 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222388; Age (years): 59; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-09-25 (29)/ 2020-09-30 (34)	Yes/ Yes/ No	4	Yes/3 (2020-09-25/ 2020-09-30)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Incision site pain/ LUMBAR PAIN AT SURGERY SITE.	2020-10-08 (42)/ 2020-10-09 (43)	Yes/ Yes/ No	4	Yes/3 (2020-10-08/ 2020-10-09)	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222400; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Kidney infection/ KIDNEY INFECTION	2020-10-10 (8)/ 2020-10-17 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222440; Age (years): 39; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-05 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222452; Age (years): 80; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Cervical vertebral fracture/ C3 CERVICAL FRACTURE	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Facial bones fracture/ NASAL FRACTURE	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Skin laceration/ FACIAL LACERATION	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Subdural haematoma/ SUBDURAL HEMATOMA	2020-10-26 (25)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222452; Age (years): 80; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-10-26 (25)/ 2020-10-30 (29)	Yes/ Yes/ No	3	Yes/3 (2020-10-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222458; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Candida infection/ THRUSH	2020-10-28 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222498; Age (years): 64; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ HARDWARE REMOVAL RIGHT FOOT SECONDARY TO FOOT FRACTURE	2020-11-09 (41)/ 2020-11-09 (41)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3222514; Age (years): 22; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-11 (2)/ 2020-10-18 (9)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222520; Age (years): 64; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Dysmenorrhoea/ DYSMENORRHEA	2020-10-12 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3222551; Age (years): 76; Sex: F; Race: WHITE							
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-10-29 (18)/ 2020-11-04 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222568; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media/ OTITIS MEDIA	2020-10-23 (10)/ 2020-10-28 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3222591; Age (years): 48; Sex: M; Race: ASIAN							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-11-19 (41)/ 2020-11-22 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3222622; Age (years): 55; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-20 (1)/ 2020-11-10 (22)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3232017; Age (years): 32; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2020-09-13 (4)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3232020; Age (years): 67; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ WORSENING AFIB EPISODE	2020-09-10 (3)/ 2020-09-11 (4)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232021; Age (years): 47; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING LOWER EXTREMETIES ARTHRALGIA	2020-08-25 (16)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232021; Age (years): 47; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING UPPER EXTREMITIES ARTHRALGIA	2020-08-25 (16)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING
Subject ID: US3232086; Age (years): 43; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-04 (15)/ 2020-09-04 (15)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-04 (15)/ 2020-09-04 (15)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232121; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-07 (11)/ 2020-09-17 (21)	Yes/ Yes/ No	3	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3232135; Age (years): 48; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-30 05:00 (1)/ 2020-09-30 13:00 (2)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3232152; Age (years): 58; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERAL MYALGIA BLES	2020-10-03 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-10-03 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3232152; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-03 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-03 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-04 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242006; Age (years): 47; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Menopausal symptoms/ HOT FLASHES/MENOPAUSAL SYMPTOMS	2020-09-06 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242006; Age (years): 47; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-09-12 (9)/ 2020-09-18 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242017; Age (years): 64; Sex: M; Race: WHITE							
Infections and infestations/ Bronchitis/ ACUTE BRONCHITIS	2020-10-17 (40)/ 2020-10-27 (50)	Yes/ Yes/ No	3	Yes/3 (2020-10-19/ 2020-10-21)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242020; Age (years): 76; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Asthma/ WORSENING OF ASTHMA	2020-08-13 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242037; Age (years): 62; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-08 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242037; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN NOS	2020-10-20 (40)/ 2020-10-21 (41)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242041; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteonecrosis/ WORSENING OF BILATERAL FEMORAL HEAD NECROSIS	2020-11-18 (70)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242043; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-08-19 (12)/ 2020-08-24 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242049; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Enterovirus infection/ ENTEROVIRUS	2020-08-18 (11)/ 2020-09-01 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242049; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ HUMAN RHINOVIRUS	2020-08-18 (11)/ 2020-09-01 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242050; Age (years): 26; Sex: M; Race: WHITE							
Infections and infestations/ Onychomycosis/ ONYCHOMYCOSIS, TOE	2020-10-19 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242059; Age (years): 70; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant melanoma/ MELANOMA, RIGHT ELBOW	2020-09-07 (27)/ 2020-09-22 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242060; Age (years): 71; Sex: F; Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA, UPPER LEFT SIDE OF FACE	2020-09-21 (12)/ 2020-10-01 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3242072; Age (years): 73; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-06 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242081; Age (years): 76; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ INSECT BITES TO LEFT LEG	2020-09-05 (24)/ 2020-09-18 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242082; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Vaginal infection/ ACUTE VAGINITIS	2020-09-07 (26)/ 2020-09-22 (41)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242082; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Cystitis/ BLADDER INFECTION	2020-09-07 (26)/ 2020-09-23 (42)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242126; Age (years): 36; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS, RIGHT FOREARM	2020-10-05 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242131; Age (years): 57; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-23 (6)/ 2020-08-28 (11)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-08-23 (6)/ 2020-08-28 (11)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242131; Age (years): 57; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-08-23 (6)/ 2020-08-28 (11)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-23 (6)/ 2020-08-29 (12)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Proctitis/ PROCTITIS	2020-08-26 (9)/ 2020-09-02 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Anal fissure/ ANAL FISSURE	2020-09-02 (16)/ 2020-09-10 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242160; Age (years): 61; Sex: M; Race: WHITE							
Infections and infestations/ Paronychia/ R. HALLUX INFECTION (PARONYCHIA)	2020-09-28 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242169; Age (years): 21; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GERD	2020-10-06 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242179; Age (years): 65; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-09-11 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242194; Age (years): 61; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Epicondylitis/ MEDIAL EPICONDYLITIS, LEFT	2020-09-07 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242198; Age (years): 70; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-14 (23)/ 2020-10-19 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242212; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Localised infection/ RIGHT INDEX FINGER INFECTION	2020-09-08 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242218; Age (years): 71; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFICIENCY	2020-10-13 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242224; Age (years): 84; Sex: M; Race: WHITE							
Infections and infestations/ Paronychia/ PARONYCHIA	2020-09-21 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242228; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Parotitis/ PAROTITIS (LEFT)	2020-10-03 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242231; Age (years): 76; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-09-01 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Vascular disorders/ Hypertension/ UNCONTROLLED HYPERTENSION	2020-09-08 (13)/ 2020-09-09 (14)	Yes/ Yes/ No	2	Yes/3 (2020-09-08/ 2020-09-09)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Aortic aneurysm/ WORSENING AORTIC ANEURYSM	2020-10-08 (14)/ 2020-10-28 (34)	Yes/ Yes/ No	3	Yes/3 (2020-10-27/ 2020-11-06)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242231; Age (years): 76; Sex: F; Race: WHITE							
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-10-15 (21)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242234; Age (years): 60; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-04 (37)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242242; Age (years): 68; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Suspected COVID-19/ POSSIBLE COVID-19	2020-11-09 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3242245; Age (years): 52; Sex: F; Race: WHITE							
Investigations/ Hormone level abnormal/ HORMONAL IMBALANCE	2020-10-02 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242269; Age (years): 77; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ CLOSED FRACTURE OF BASE OF 5TH METATARSAL BONE, LEFT FOOT	2020-10-02 (3)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA EXACERBATION	2020-10-15 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Acute sinusitis/ ACUTE FRONTAL SINUSITIS	2020-10-29 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242273; Age (years): 66; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-15 (15)/ 2020-09-19 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242273; Age (years): 66; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-15 (15)/ 2020-09-19 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242284; Age (years): 20; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-10-15 (14)/ 2020-10-23 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242288; Age (years): 58; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ WORSENING HYPERLIPIDEMIA	2020-09-29 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3242303; Age (years): 31; Sex: F; Race: OTHER: (b) (6)							
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFICIENCY	2020-09-25 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242314; Age (years): 75; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATIC ADENOCARCINOMA (GLEASON SCORE 3+4+=7)	2020-11-06 (29)/ Ongoing	Yes/ Yes/ No	3	Yes/2	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242321; Age (years): 35; Sex: F; Race: MULTIPLE: (b) (6)							
Gastrointestinal disorders/ Umbilical hernia/ UMBILICAL HERNIA	2020-10-13 10:00 (1)/ 2020-10-17 (6)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3242329; Age (years): 43; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Reproductive system and breast disorders/ Gynaecomastia/ GYNECOMASTIA, RIGHT BREAST	2020-10-26 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3242333; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Conjunctivitis/ B/L EYE CONJUNCTIVITIS	2020-10-05 (21)/ 2020-10-13 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3242337; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Anxiety/ INCREASED ANXIETY	2020-09-17 09:30 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-11-04 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3242370; Age (years): 28; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Schizoaffective disorder/ WORSENING OF SCHIZOAFFECTIVE DISORDER	2020-09-29 (7)/ 2020-10-03 (11)	Yes/ Yes/ No	3	Yes/2/3 (2020-09-29/ 2020-10-03)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252008; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-03 (6)/ 2020-09-14 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252051; Age (years): 45; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-09 (7)/ 2020-09-16 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252071; Age (years): 58; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-18 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252075; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-08-13 (7)/ 2020-08-20 (14)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252081; Age (years): 80; Sex: M; Race: WHITE							
Vascular disorders/ Deep vein thrombosis/ LEFT LEG DEEP VEIN THROMBOSIS	2020-11-12 (70)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252111; Age (years): 45; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT SUPRACLAVICULAR, ANTERIOR CERVICAL AND POSTAURICULAR LYMPHADENOPATHY	2020-08-18 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ R	DOSE DELAYED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ RIGHT AXILLARY LYMPHADENOPATHY	2020-09-10 00:00 (1)/ 2020-10-06 (28)	Yes/ Yes/ Yes	1	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252127; Age (years): 68; Sex: M; Race: WHITE							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-10-28 (51)/ 2020-10-29 (52)	Yes/ Yes/ No	3	Yes/3 (2020-10-28/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3252136; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-29 (18)/ 2020-09-05 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252149; Age (years): 68; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Adenomyosis/ ADENOMYOSIS	2020-10-05 (25)/ 2020-10-05 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252166; Age (years): 50; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Thyroid cancer metastatic/ METASTATIC PAPILLARY THYROID CARCINOMA	2020-09-22 (13)/ 2020-10-30 (51)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Endocrine disorders/ Hypothyroidism/ HYPOTHYROIDISM	2020-10-30 (51)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Endocrine disorders/ Thyroid disorder/ THYROIDECTOMY	2020-11-01 (53)/ 2020-11-01 (53)	Yes/ Yes/ No	3	Yes/3 (2020-10-30/ 2020-11-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252210; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-09-19 07:30 (33)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3252239; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-09-21 (7)/ 2020-09-28 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252244; Age (years): 60; Sex: F; Race: WHITE							
Vascular disorders/ Hypertensive urgency/ HYPERTENSIVE URGENCY	2020-10-13 (26)/ 2020-10-13 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252261; Age (years): 75; Sex: F; Race: WHITE							
Cardiac disorders/ Cardiac failure/ HEART FAILURE	2020-11-01 (47)/ 2020-11-03 (49)	Yes/ Yes/ No	4	Yes/3 (2020-11-01/ 2020-11-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252286; Age (years): 47; Sex: F; Race: NOT REPORTED							
Vascular disorders/ Hypertensive urgency/ HYPERTENSIVE URGENCY	2020-09-23 19:00 (2)/ 2020-09-24 00:00 (2)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252302; Age (years): 50; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEFT SIDED BACK SPASM	2020-09-26 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252324; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Helicobacter infection/ HELICOBACTER PYLORI INFECTION	2020-09-26 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252396; Age (years): 54; Sex: M; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-09-29 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252494; Age (years): 49; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-10-03 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Depression/ DEPRESSION	2020-10-03 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252516; Age (years): 40; Sex: M; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Colitis/ COLITIS	2020-09-30 00:00 (9)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-30/ 2020-10-08)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252516; Age (years): 40; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-09-30 00:00 (9)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-09-30/ 2020-10-08)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3252527; Age (years): 32; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-09-24 (3)/ 2020-10-23 (32)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252532; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ DENTAL ABSCESS	2020-10-19 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3252567; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Large intestine infection/ INFECTIOUS COLITIS	2020-10-21 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3252606; Age (years): 22; Sex: M; Race: WHITE							
Hepatobiliary disorders/ Cholelithiasis/ CHOLELITHIASIS	2020-10-12 (11)/ 2020-10-12 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3252610; Age (years): 25; Sex: F; Race: ASIAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-05 (7)/ 2020-11-12 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3252685; Age (years): 44; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-01 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3262056; Age (years): 66; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Colitis/ INTERMITTENT COLITIS OF UNKNOWN ETIOLOGY	2020-10-24 (58)/	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3262133; Age (years): 58; Sex: F; Race: WHITE							
Immune system disorders/ Anaphylactic reaction/ ANAPHYLAXIS	2020-11-07 08:30 (63)/ 2020-11-07 08:45 (63)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272013; Age (years): 31; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-09 (72)/ 2020-10-09 (72)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-09 (72)/ 2020-10-09 (72)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-09 (72)/ 2020-10-09 (72)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272014; Age (years): 50; Sex: F; Race: WHITE							
Endocrine disorders/ Hypothyroidism/ WORSENING OF HYPOTHYROIDISM	2020-08-26 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272027; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS OF POSTERIOR NECK	2020-09-29 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN IN POSTERIOR NECK	2020-09-29 (6)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272027; Age (years): 66; Sex: F; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA EPISODE	2020-09-29 (6)/ 2020-09-29 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION (WORSENING)	2020-09-30 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272065; Age (years): 37; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ WORSENING OF MIGRAINES	2020-09-02 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272067; Age (years): 27; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-11 (39)/ 2020-10-22 (50)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272067; Age (years): 27; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-11 (39)/ 2020-10-24 (52)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272076; Age (years): 61; Sex: F; Race: WHITE							
Endocrine disorders/ Hypothyroidism/ HYPOTHYROIDISM	2020-09-22 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Joint injury/ RIGHT KNEE INJURY	2020-10-03 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272084; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272084; Age (years): 62; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-16 (13)/ 2020-09-16 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-09-16 (13)/ 2020-09-16 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-16 (13)/ 2020-09-19 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-16 (13)/ 2020-09-20 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272084; Age (years): 62; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-16 (13)/ 2020-09-20 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272096; Age (years): 31; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-09-23 (15)/ 2020-09-23 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272122; Age (years): 64; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF BILATERAL KNEE PAIN	2020-10-19 (39)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272123; Age (years): 37; Sex: F; Race: WHITE							
Immune system disorders/ Seasonal allergy/ SEASONAL ALLERGIES	2020-08-23 (12)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272124; Age (years): 55; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain lower/ LEFT LOWER QUADRANT PAIN	2020-10-15 (36)/ 2020-10-15 (36)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-15 (36)/ 2020-10-15 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Flank pain/ LEFT FLANK PAIN	2020-10-15 (36)/ 2020-10-15 (36)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272128; Age (years): 72; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Inguinal hernia/ BILATERAL INGUINAL HERNIA	2020-09-24 (15)/ 2020-10-13 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3272137; Age (years): 56; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-18 (1)/ 2020-10-14 (27)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Foot fracture/ BROKEN R FOOT	2020-10-03 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-11 (24)/ 2020-10-20 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272140; Age (years): 25; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-05 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-05 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID-LIKE ILLNESS	2020-11-07 (54)/ 2020-11-18 (65)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272167; Age (years): 28; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ WORSENING MAXILLARY CAVITIES	2020-10-07 (24)/ 2020-10-07 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Gastric ulcer/ GASTRIC ULCER	2020-10-07 (24)/ 2020-10-12 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-11 (28)/ 2020-10-12 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ EMESIS	2020-10-11 (28)/ 2020-10-12 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272169; Age (years): 47; Sex: F; Race: WHITE							
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-08-20 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Rectal prolapse/ RECTAL PROLAPSE	2020-09-08 (25)/ 2020-09-08 (25)	Yes/ Yes/ No	4	Yes/3 (2020-10-19/ 2020-10-24)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Rectal prolapse/ RECTAL PROLAPSE REPAIR COMPLICATION DUE TO CONSTIPATION	2020-11-05 (51)/ 2020-11-07 (53)	Yes/ Yes/ No	3	Yes/3 (2020-11-05/ 2020-11-07)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272173; Age (years): 28; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ DENTAL CARIES - UPPER RIGHT LATER TOOTH	2020-10-01 (18)/ 2020-10-29 (46)	Yes/ Yes/ No			NR/ NR	/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272180; Age (years): 32; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-08-18 (1)/ 2020-08-24 (7)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272199; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-10 (23)/ 2020-10-12 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-10 (23)/ 2020-10-12 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-10 (23)/ 2020-10-14 (27)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272199; Age (years): 46; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-10 (23)/ 2020-10-14 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-10 (23)/ 2020-10-14 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-10 (23)/ 2020-10-14 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Magnesium deficiency/ MAGNESIUM DEFICIENCY	2020-10-12 (25)/ 2020-10-12 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272199; Age (years): 46; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-12 (25)/ 2020-10-12 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272204; Age (years): 71; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272204; Age (years): 71; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (GENERALIZED)	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272204; Age (years): 71; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272204; Age (years): 71; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-21 (2)/ 2020-08-25 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-08-21 (2)/ 2020-08-27 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272235; Age (years): 54; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-19 (2)/ 2020-09-21 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272235; Age (years): 54; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-19 (2)/ 2020-09-21 (4)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-19 (2)/ 2020-09-21 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-19 (2)/ 2020-09-23 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272235; Age (years): 54; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-19 (2)/ 2020-09-23 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272237; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-30 (43)/ 2020-11-05 (49)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272240; Age (years): 56; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-02 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272240; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-02 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-10-02 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-02 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-02 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272255; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ LEFT EAR INFECTION	2020-10-22 (35)/ 2020-10-23 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272260; Age (years): 30; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-08-22 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272264; Age (years): 60; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-03 (9)/ 2020-10-08 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-03 (9)/ 2020-10-16 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272264; Age (years): 60; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-03 (9)/ 2020-10-16 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-03 (9)/ 2020-10-16 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-11 (17)/ 2020-10-16 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272265; Age (years): 42; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPAMS (LOWER BACK)	2020-09-02 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272273; Age (years): 49; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-08-30 (9)/ 2020-09-01 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272279; Age (years): 33; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING OF ANXIETY	2020-09-17 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3272299; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID-LIKE ILLNESS	2020-11-14 (51)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272304; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-29 (38)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272312; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTION LEFT LEG	2020-08-26 (4)/ 2020-09-09 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3272312; Age (years): 60; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ LEFT SHOULDER INJURY AT WORK ON 18SEP2020. IT HAS BEEN HURTING SINCE THEN. SEEN THE ORTHO PHYSICIAN ON THURSDAY 08OCT2020 AND THEN WENT TO PHYSICAL THERAPY 09OCT2020.	2020-09-18 (27)/ 2020-11-21 (91)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3272325; Age (years): 33; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-11 (48)/ 2020-11-12 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-11-11 (48)/ 2020-11-12 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272325; Age (years): 33; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-11 (48)/ 2020-11-18 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-12 (49)/ 2020-11-18 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-12 (49)/ 2020-11-18 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-12 (49)/ 2020-11-18 (55)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3272325; Age (years): 33; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-11-12 (49)/ 2020-11-18 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-12 (49)/ 2020-11-18 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-11-12 (49)/ 2020-11-18 (55)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3272325; Age (years): 33; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-11-12 (49)/ 2020-11-20 (57)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-13 (50)/ 2020-11-17 (54)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
			1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIAS	2020-11-13 (50)/ 2020-11-17 (54)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272327; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-24 (33)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Infections and infestations/ Sinusitis/ SINUSITIS	2020-09-27 (3)/ 2020-10-02 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERLAIZED MUSCLE ACHES	2020-10-07 (13)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272327; Age (years): 61; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-07 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-07 (13)/ 2020-10-09 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-07 (13)/ 2020-10-09 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-07 (13)/ 2020-10-09 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272327; Age (years): 61; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-07 (13)/ 2020-10-09 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-07 (13)/ 2020-10-09 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-07 (13)/ 2020-10-09 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272327; Age (years): 61; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-09 (15)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-10-09 (15)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3272335; Age (years): 69; Sex: M; Race: WHITE							
Surgical and medical procedures/ Influenza immunisation/ INFLUENZA VACCINE	2020-10-29 (34)/ 2020-10-29 (34)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272337; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS - LEFT LEG	2020-09-16 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272337; Age (years): 63; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Diabetes mellitus/ WORSENING OF TYPE 2 DIABETES MELETUS	2020-10-27 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272343; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-07 (16)/ 2020-09-14 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-09 (18)/ 2020-09-17 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272343; Age (years): 46; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES (WHOLE BODY)	2020-09-09 (18)/ 2020-09-17 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-09 (18)/ 2020-09-17 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-09 (18)/ 2020-09-19 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272343; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 (18)/ 2020-09-20 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-09 (18)/ 2020-09-20 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-09 (18)/ 2020-09-20 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-09 (18)/ 2020-09-20 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272343; Age (years): 46; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-09 (18)/ 2020-09-20 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-15 (24)/ 2020-09-17 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-15 (24)/ 2020-09-20 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypotension/ HYPOTENSION	2020-11-06 (47)/ 2020-11-08 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272353; Age (years): 66; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ CAT BITE	2020-10-27 (37)/ 2020-11-06 (47)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3272364; Age (years): 30; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Abdominal pain/ WORSENING INTERMITTENT ABDOMINAL PAIN	2020-10-09 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Diarrhoea/ WORSENING INTERMITTENT DIARRHEA	2020-10-09 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3272367; Age (years): 64; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ NON-CARDIAC RESPIRATORY CHEST CONGESTION	2020-10-11 (14)/ 2020-10-21 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3272371; Age (years): 62; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ WORSENING OF TYPE 2 DIABETES MELLITUS	2020-10-29 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3272376; Age (years): 45; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-03 (22)/ 2020-11-08 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282018; Age (years): 78; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Skin cancer/ SKIN CANCER, UNSPECIFIED	2020-08-19 (13)/ 2020-09-10 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3282043; Age (years): 79; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-10 (27)/ 2020-10-23 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3282047; Age (years): 85; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ AVULSION OF THIRD DIGIT OF LEFT HAND	2020-09-21 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282050; Age (years): 75; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-08-15 (3)/ 2020-08-30 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3282063; Age (years): 43; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-15 20:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-15 20:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3282074; Age (years): 72; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ DECAYED TOOTH	2020-09-22 09:00 (1)/ 2020-09-22 15:00 (2)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282087; Age (years): 67; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ LEFT FOOT PAIN, POST-SURGICAL	2020-09-11 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3282113; Age (years): 66; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE	2020-10-23 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-10-23 (8)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-23/ 2020-10-25)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282113; Age (years): 66; Sex: M; Race: WHITE							
Renal and urinary disorders/ Renal cyst/ CYSTIC LESION WITHIN LEFT KIDNEY	2020-10-23 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ WORSENING OF MIDSTERNAL CHEST PAIN	2020-10-23 (8)/ 2020-10-23 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural pain/ POST CORONARY ARTERY BYPASS GRAFT PAIN	2020-11-02 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3282113; Age (years): 66; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY THROMBOEMBOLISM	2020-11-06 (22)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-06/ 2020-11-10)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292003; Age (years): 70; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-05 (6)/ 2020-08-09 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292008; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-01 (31)/ 2020-10-05 (35)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292023; Age (years): 80; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Diabetic ketoacidosis/ DIABETIC KETOACIDOSIS	2020-10-22 (52)/ 2020-10-26 (56)	Yes/ Yes/ No	3	Yes/3 (2020-10-22/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292025; Age (years): 42; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-04 (4)/ 2020-09-06 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292055; Age (years): 49; Sex: F; Race: WHITE							
Hepatobiliary disorders/ Cholelithiasis/ CHOLELITHIASIS	2020-08-16 (9)/ 2020-08-27 (20)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3292057; Age (years): 65; Sex: F; Race: WHITE							
Vascular disorders/ Hypertensive emergency/ HYPERTENSIVE EMERGENCY	2020-10-01 (29)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292062; Age (years): 43; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ RIGHT FOOT WOUND	2020-09-29 (27)/ 2020-10-07 (35)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292062; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS	2020-11-14 (73)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292068; Age (years): 66; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-07 (3)/ 2020-09-07 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-07 (3)/ 2020-09-07 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-09-07 (3)/ 2020-09-07 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292077; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-10-03 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292080; Age (years): 69; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Angiolipoma/ ANGIOLIPOMA	2020-09-22 (15)/ 2020-09-29 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3292086; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-02 (30)/ 2020-10-02 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-02 (30)/ 2020-10-04 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292086; Age (years): 62; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-02 (30)/ 2020-10-04 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292087; Age (years): 50; Sex: F; Race: WHITE							
Nervous system disorders/ Paraesthesia/ TINGLE SENSATION ON LEFT FOREARM, ELBOW AND HAND.	2020-09-13 (11)/ 2020-09-17 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292103; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Subdural haematoma/ SUBDURAL HEMATOMA	2020-11-14 (71)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-15/ 2020-11-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292112; Age (years): 67; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ TORN L ROTATOR CUFF	2020-09-15 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292113; Age (years): 52; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-06 (60)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292130; Age (years): 67; Sex: M; Race: WHITE							
Vascular disorders/ Hot flush/ HOT FLASHES	2020-10-05 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-06 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292131; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Humerus fracture/ R HUMERUS FRACTURE	2020-10-22 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3292133; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bursitis/ BURSITIS OF RIGHT KNEE	2020-08-31 (21)/ 2020-09-21 (42)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Tooth fracture/ BROKEN TOOTH	2020-11-05 (59)/ 2020-11-09 (63)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3292137; Age (years): 18; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Dislocation of vertebra/ DISLOCATED TAILBONE	2020-10-20 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292145; Age (years): 67; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal septum deviation/ DEVIATED SEPTUM	2020-10-01 (20)/ 2020-10-19 (38)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292156; Age (years): 43; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spondylolysis/ PARS DEFECT L5 S1	2020-10-07 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292174; Age (years): 64; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament rupture/ TORN LIGAMENT IN LEFT KNEE	2020-08-29 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292174; Age (years): 64; Sex: M; Race: WHITE							
Infections and infestations/ Tooth infection/ LOWER R MOLAR INFECTION	2020-09-01 (18)/ 2020-09-28 (45)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Limb mass/ MASS ON LEFT KNEE	2020-10-15 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-10-31 (50)/ 2020-11-05 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292181; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ RIGHT EAR INFECTION	2020-10-10 (26)/ Ongoing	Yes/ Yes/ No	2		NR/ NR		
Subject ID: US3292197; Age (years): 53; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ BROKEN TOE	2020-09-20 (6)/ 2020-11-11 (58)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292200; Age (years): 75; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-14 (33)/ 2020-10-21 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292203; Age (years): 69; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Inguinal hernia/ HERNIA IN GROIN	2020-09-28 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292244; Age (years): 64; Sex: M; Race: WHITE							
Eye disorders/ Eye haemorrhage/ LEFT EYE BROKEN BLOOD VESSEL	2020-10-31 (45)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3292253; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-06 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ MUSCULOSKELETAL PAIN	2020-11-06 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292256; Age (years): 76; Sex: F; Race: WHITE							
Infections and infestations/ Cystitis/ BLADDER INFECTION	2020-10-02 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292274; Age (years): 64; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL ON RIGHT ARM	2020-08-31 (11)/ 2020-10-12 (53)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Tendonitis/ ELBOW TENDONITIS	2020-09-17 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Surgical and medical procedures/ Tooth extraction/ TOOTH EXTRACTION	2020-10-14 (26)/ 2020-10-21 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292279; Age (years): 51; Sex: F; Race: WHITE							
Nervous system disorders/ Head discomfort/ HEAD PRESSURE	2020-11-05 (48)/ 2020-11-12 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dysphonia/ HOARSENESS OF VOICE	2020-11-05 (48)/ 2020-11-12 (55)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-05 (48)/ 2020-11-12 (55)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292279; Age (years): 51; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Paranasal sinus discomfort/ SINUS PRESSURE	2020-11-05 (48)/ 2020-11-12 (55)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Bronchitis/ ACUTE BRONCHITIS	2020-11-12 (55)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS	2020-11-12 (55)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3292284; Age (years): 71; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ L AXILLARY LYMPADENOPATHY	2020-08-23 (3)/ 2020-10-31 (72)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292304; Age (years): 35; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Large intestine perforation/ PERFORATED COLON	2020-10-04 (13)/ 2020-10-06 (15)	Yes/ Yes/ No	3	Yes/3 (2020-10-04/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2020-10-07 (16)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-10-04/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3292312; Age (years): 56; Sex: M; Race: WHITE							
Nervous system disorders/ Cerebrovascular accident/ STROKE	2020-10-25 (34)/ 2020-10-25 (34)	Yes/ Yes/ No	4	Yes/3 (2020-10-25/ 2020-10-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Subject ID: US3292316; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Abscess limb/ L FOOT ABCESS	2020-10-16 (25)/ 2020-10-18 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3292321; Age (years): 44; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin ulcer/ ULCER ON BOTTOM OF RIGHT FOOT	2020-10-01 (10)/ 2020-10-10 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3292324; Age (years): 66; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Femur fracture/ R BROKEN FEMUR	2020-11-03 (41)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Subject ID: US3292365; Age (years): 58; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Invasive lobular breast carcinoma/ INVASIVE LOBULAR BREAST CARCINOMA	2020-10-08 (13)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292366; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-20 (23)/ 2020-09-27 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/	RECOVERED/ RESOLVED
Subject ID: US3292412; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19	2020-09-25 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292422; Age (years): 53; Sex: F; Race: WHITE							
Hepatobiliary disorders/ Cholelithiasis/ GALLSTONES	2020-10-12 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3292422; Age (years): 53; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ ENLARGED LYMPH NODE - RIGHT UNDERAM	2020-10-12 (14)/ 2020-10-16 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3292429; Age (years): 51; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ SESAMOIDITIS	2020-10-15 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3292442; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ Enterovirus infection/ ENTEROVIRUS	2020-11-15 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Infections and infestations/ Rhinovirus infection/ HUMAN RHINO VIRUS	2020-11-15 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302002; Age (years): 76; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-26 (57)/ 2020-10-28 (59)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3302024; Age (years): 34; Sex: F; Race: WHITE							
Endocrine disorders/ Thyroid mass/ THYROID LUMP	2020-11-07 (68)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3302027; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Cellulitis/ CELLULITIS	2020-11-13 (75)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3302111; Age (years): 65; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA	2020-10-21 (42)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302130; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-08-24 (15)/ 2020-08-30 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3302172; Age (years): 57; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT FLANK PAIN	2020-08-30 (19)/ 2020-09-02 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3302200; Age (years): 62; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS	2020-08-14 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3302207; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-11-20 (71)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302207; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-20 (71)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-11-20 (71)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3302320; Age (years): 47; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-11 (55)/ 2020-11-13 (57)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3302332; Age (years): 55; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-19 (60)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3302357; Age (years): 63; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-08 (48)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	2020-11-08 (48)/ 2020-11-11 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-08 (48)/ 2020-11-11 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3302361; Age (years): 57; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-09 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312021; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-27 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Immune system disorders/ Drug hypersensitivity/ ALLERGIC REACTION TO BACTRIM	2020-10-05 (29)/ 2020-10-09 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312023; Age (years): 66; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Wrist fracture/ LEFT WRIST FRACTURE	2020-08-14 (4)/ 2020-09-25 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-02 (25)/ 2020-10-06 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312023; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-02 (25)/ 2020-10-06 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-02 (25)/ 2020-10-06 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-02 (25)/ 2020-10-06 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-02 (25)/ 2020-10-06 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312023; Age (years): 66; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-02 (25)/ 2020-10-06 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (25)/ 2020-10-15 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-02 (25)/ 2020-10-19 (42)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312023; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-08 (31)/ 2020-10-15 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Anosmia/ NEW LOSS OF SMELL	2020-10-08 (31)/ 2020-10-15 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-10-08 (31)/ 2020-10-15 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-08 (31)/ 2020-10-15 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312023; Age (years): 66; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-08 (31)/ 2020-10-15 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-08 (31)/ 2020-10-15 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-08 (31)/ 2020-10-17 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-08 (31)/ 2020-10-19 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312041; Age (years): 32; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-31 (53)/ 2020-11-08 (61)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-31 (53)/ 2020-11-10 (63)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312043; Age (years): 20; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-29 (18)/ 2020-09-10 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-31 (20)/ 2020-09-03 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312043; Age (years): 20; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-03 (23)/ 2020-09-07 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-03 (23)/ 2020-09-10 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-05 (25)/ 2020-09-12 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-06 (26)/ 2020-09-09 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312043; Age (years): 20; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-06 (26)/ 2020-09-09 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ PLEURITIC CHEST PAIN	2020-09-06 (26)/ 2020-09-10 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-07 (27)/ 2020-09-09 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312043; Age (years): 20; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-09 (29)/ 2020-09-10 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (2)/ 2020-09-21 (7)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312046; Age (years): 82; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-10-07 (29)/ 2020-10-07 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-07 (29)/ 2020-10-07 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3312046; Age (years): 82; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-07 (29)/ 2020-10-14 (36)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-07 (29)/ 2020-10-16 (38)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-07 (29)/ 2020-10-19 (41)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Viral pharyngitis/ VIRAL PHARYNGITIS	2020-10-07 (29)/ 2020-11-15 (68)	Yes/ Yes/ No	2	Yes/3 (2020-10-07/ 2020-10-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3312046; Age (years): 82; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-09 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-18 (40)/ 2020-10-18 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-18 (40)/ 2020-10-20 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312063; Age (years): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-08-21 (9)/ 2020-08-26 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312063; Age (years): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-21 (9)/ 2020-08-28 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-21 (9)/ 2020-08-28 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312063; Age (years): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-08-21 (9)/ 2020-08-28 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-08-21 (9)/ 2020-09-15 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Ageusia/ NEW LOSS OF TASTE	2020-08-21 (9)/ 2020-09-15 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Anosmia/ NEW LOSS OF SMELL	2020-08-21 (9)/ 2020-09-15 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312063; Age (years): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-08-25 (13)/ 2020-08-26 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-08-25 (13)/ 2020-08-28 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-26 (14)/ 2020-08-26 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312091; Age (years): 24; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-20 (7)/ 2020-09-22 (9)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312105; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ BACK MUSCLE STRAIN	2020-10-10 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3312106; Age (years): 23; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-30 (17)/ 2020-10-05 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-30 (17)/ 2020-10-05 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312106; Age (years): 23; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-30 (17)/ 2020-10-07 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-30 (17)/ 2020-10-08 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-30 (17)/ 2020-10-08 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-09-30 (17)/ 2020-10-09 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312106; Age (years): 23; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-02 (19)/ 2020-10-03 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312120; Age (years): 56; Sex: F; Race: WHITE							
Nervous system disorders/ Cervical radiculopathy/ CERVICAL RADICULOPATHY	2020-11-01 (48)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312147; Age (years): 51; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Hand fracture/ FOURTH MIDDLE PHALANX FRACTURE	2020-10-03 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312157; Age (years): 21; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ FACIAL ACNE	2020-09-25 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312161; Age (years): 45; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-21 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNING NOSE	2020-09-23 (8)/ 2020-09-23 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-15 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312180; Age (years): 25; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-25 (35)/ 2020-10-25 (35)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312180; Age (years): 25; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-25 (35)/ 2020-10-26 (36)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-25 (35)/ 2020-10-30 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-25 (35)/ 2020-10-31 (41)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Enterovirus infection/ ENTEROVIRUS	2020-10-25 (35)/ 2020-11-01 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312180; Age (years): 25; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-10-25 (35)/ 2020-11-01 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-25 (35)/ 2020-11-01 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-28 (38)/ 2020-10-31 (41)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312186; Age (years): 74; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-25 (39)/ 2020-10-27 (41)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312186; Age (years): 74; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-25 (39)/ 2020-10-28 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-26 (40)/ 2020-10-28 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-27 (41)/ 2020-10-28 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312189; Age (years): 63; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-02 (16)/ 2020-10-02 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312189; Age (years): 63; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-05 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-06 (20)/ 2020-11-01 (46)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312197; Age (years): 69; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY EXACERBATION	2020-08-25 (6)/ 2020-08-25 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Cervical radiculopathy/ EXACERBATION OF LEFT CERVICAL RADICULOPATHY	2020-09-06 (18)/ 2020-10-09 (51)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312211; Age (years): 38; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Fibrocystic breast disease/ FIBROCYSTIC BREAST DISEASE	2020-09-18 12:58 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Headache/ HEADACHE	2020-09-28 (11)/ 2020-10-06 (19)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-29 (12)/ 2020-10-01 (14)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312211; Age (years): 38; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-29 (12)/ 2020-10-01 (14)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-29 (12)/ 2020-10-05 (18)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-29 (12)/ 2020-10-08 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312211; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-04 (17)/ 2020-10-04 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-04 (17)/ 2020-10-04 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-04 (17)/ 2020-10-05 (18)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312211; Age (years): 38; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ CERVICAL SHOTTY LYMPHADENOPATHY	2020-10-05 (18)/ 2020-11-04 (48)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-30 (43)/ 2020-11-08 (52)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-31 (44)/ 2020-11-06 (50)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312211; Age (years): 38; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-31 (44)/ 2020-11-06 (50)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-31 (44)/ 2020-11-08 (52)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-11-04 (48)/ 2020-11-08 (52)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-05 (49)/ 2020-11-05 (49)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312211; Age (years): 38; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-05 (49)/ 2020-11-05 (49)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-06 (50)/ 2020-11-06 (50)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312213; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-10 (23)/ 2020-10-19 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-13 (26)/ 2020-10-16 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312213; Age (years): 70; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-13 (26)/ 2020-10-16 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312218; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-16 (30)/ 2020-10-28 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312221; Age (years): 63; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rosacea/ EXACERBATION OF ROSACEA	2020-11-01 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312242; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Rhinitis/ NASAL INFECTION	2020-10-19 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312242; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-19 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-19 (32)/ 2020-10-19 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-19 (32)/ 2020-10-19 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-19 (32)/ 2020-10-21 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312242; Age (years): 59; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-19 (32)/ 2020-10-22 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-19 (32)/ 2020-10-28 (41)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-19 (32)/ 2020-10-28 (41)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-27 (40)/ 2020-10-27 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312242; Age (years): 59; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-27 (40)/ 2020-10-27 (40)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-27 (40)/ 2020-10-28 (41)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-28 (41)/ 2020-10-28 (41)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312249; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Gastrointestinal infection/ INTESTINAL INFECTION	2020-09-23 (31)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312253; Age (years): 73; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-03 (13)/ 2020-10-05 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-03 (13)/ 2020-10-08 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 (13)/ 2020-10-08 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-03 (13)/ 2020-10-08 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312253; Age (years): 73; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-07 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312263; Age (years): 40; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-03 (12)/ 2020-10-12 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-04 (13)/ 2020-10-04 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312266; Age (years): 51; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ EXACERBATION OF ANXIETY	2020-10-03 (12)/ 2020-11-15 (55)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312275; Age (years): 56; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pityriasis rosea/ PITYRIASIS ROSEA	2020-09-08 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312287; Age (years): 26; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-20 (28)/ 2020-10-23 (31)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-20 (28)/ 2020-11-06 (45)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-20 (28)/ 2020-11-06 (45)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312287; Age (years): 26; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-20 (28)/ 2020-11-06 (45)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312298; Age (years): 74; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-03 (9)/ 2020-09-20 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312333; Age (years): 38; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-20 (27)/ 2020-10-23 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-21 (28)/ 2020-10-22 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312333; Age (years): 38; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-24 (31)/ 2020-10-24 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312344; Age (years): 67; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-08 (16)/ 2020-10-13 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-08 (16)/ 2020-10-14 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-08 (16)/ 2020-10-15 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312344; Age (years): 67; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-08 (16)/ 2020-10-17 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-04 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312355; Age (years): 28; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING ANXIETY	2020-09-22 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-15 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312363; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Paronychia/ PARONYCHIA	2020-09-27 (3)/ 2020-11-10 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312367; Age (years): 58; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH	2020-09-28 (4)/ 2020-10-04 (10)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312372; Age (years): 37; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ DEPRESSION EXACERBATION	2020-10-15 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312379; Age (years): 27; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ NECK STRAIN	2020-09-04 (8)/ 2020-09-15 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312379; Age (years): 27; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-11 (15)/ 2020-09-12 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-11 (15)/ 2020-09-14 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-11 (15)/ 2020-09-21 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-12 (16)/ 2020-09-17 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312379; Age (years): 27; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-15 (19)/ 2020-09-19 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Bronchiectasis/ EXACERBATION OF BRONCHIECTASIS	2020-09-15 (19)/ 2020-09-21 (25)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-15 (19)/ 2020-09-21 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312379; Age (years): 27; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-21 (27)/ 2020-10-28 (34)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-27 (33)/ 2020-10-27 (33)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-28 (34)/ 2020-10-28 (34)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-28 (34)/ 2020-10-29 (35)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312379; Age (years): 27; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFCULTY BREATHING	2020-10-29 (35)/ 2020-11-03 (40)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-29 (35)/ 2020-11-03 (40)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Ageusia/ LOSS OF TASTE	2020-10-29 (35)/ 2020-11-05 (42)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Anosmia/ LOSS OF SMELL	2020-10-29 (35)/ 2020-11-05 (42)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3312379; Age (years): 27; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Bronchiectasis/ EXACERBATION OF BRONCHIECTASIS	2020-10-29 (35)/ 2020-11-08 (45)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312389; Age (years): 66; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT ANTERIOR CERVICAL CHAIN LYMPHADENOPATHY	2020-09-19 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-19 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312389; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Enterovirus infection/ ENTEROVIRUS	2020-09-22 (23)/ 2020-09-24 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Oesophagitis/ ESOPHAGITIS	2020-11-11 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312394; Age (years): 58; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Chondrocalcinosis pyrophosphate/ CALCIUM PYROPHOSPHATE DIHYDRATE CRYSTAL DEPOSITION DISEASE	2020-11-04 (38)/ 2020-11-11 (45)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3312419; Age (years): 40; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Iron deficiency anaemia/ EXACERBATION OF IRON DEFICIENCY ANEMIA	2020-09-25 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312428; Age (years): 40; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-18 (18)/ 2020-09-23 (23)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 (19)/ 2020-09-20 (20)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-19 (19)/ 2020-09-23 (23)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312428; Age (years): 40; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-19 (19)/ 2020-09-23 (23)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-24 (24)/ 2020-09-24 (24)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-24 (24)/ 2020-09-24 (24)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312428; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-04 (37)/ 2020-11-18 (51)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312435; Age (years): 62; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ EXACERBATION OF LOW BACK STRAIN	2020-10-02 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Congenital, familial and genetic disorders/ Dermoid cyst/ EPIDERMOID CYST TO BACK	2020-10-05 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312463; Age (years): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-10-01 (2)/ 2020-10-01 (2)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-01 (2)/ 2020-10-01 (2)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-01 (2)/ 2020-10-02 (3)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-01 (2)/ 2020-10-03 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312463; Age (years): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-01 (2)/ 2020-10-03 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-01 (2)/ 2020-10-03 (4)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-01 (2)/ 2020-10-03 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-01 (2)/ 2020-10-05 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312463; Age (years): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-02 (3)/ 2020-10-02 (3)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-05 (6)/ 2020-10-06 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-05 (6)/ 2020-10-06 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-05 (6)/ 2020-10-07 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312463; Age (years): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-08 (9)/ 2020-10-08 (9)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312477; Age (years): 58; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-27 (26)/ 2020-10-28 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-27 (26)/ 2020-10-28 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-27 (26)/ 2020-11-08 (38)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312477; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ Enterovirus infection/ ENTEROVIRUS	2020-10-27 (26)/ 2020-11-14 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-10-27 (26)/ 2020-11-14 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-29 (28)/ 2020-11-14 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-31 (30)/ 2020-10-31 (30)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312477; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-11-01 (31)/ 2020-11-04 (34)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312485; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-04 (35)/ 2020-11-04 (35)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-04 (35)/ 2020-11-06 (37)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-05 (36)/ 2020-11-06 (37)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312485; Age (years): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-11-06 (37)/ 2020-11-06 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	2020-11-07 (38)/ 2020-11-07 (38)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-07 (38)/ 2020-11-07 (38)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3312499; Age (years): 63; Sex: F; Race: WHITE							
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE	2020-10-29 (29)/ 2020-10-29 (29)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312524; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-20 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 (19)/ 2020-10-23 (22)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312537; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-09-10 (3)/ 2020-09-20 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312545; Age (years): 53; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	2020-09-25 (18)/ 2020-09-27 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312556; Age (years): 20; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-11 (5)/ 2020-10-17 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-11 (5)/ 2020-10-20 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-12 (6)/ 2020-10-23 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-16 (10)/ 2020-10-16 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312593; Age (years): 60; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenitis/ IPSILATERAL UNDERARM GLAND SWELLING	2020-10-08 (1)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3312596; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ LOWER RIGHT BACK TOOTH INFECTION	2020-09-30 (21)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3312598; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-06 (27)/ 2020-10-19 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3312615; Age (years): 63; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN (SUSPECTED GASTROESOPHAGEAL REFLUX DISEASE RELATED)	2020-09-24 (15)/ 2020-09-27 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3312617; Age (years): 51; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ DENTAL CARIES	2020-10-06 (26)/ 2020-10-06 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3312637; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Coronary artery disease/ EXACERBATION OF CORONARY ARTERY DISEASE	2020-10-15 (35)/ 2020-10-16 (36)	Yes/ Yes/ No	2	Yes/3 (2020-10-15/ 2020-10-16)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322026; Age (years): 50; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-06 (22)/ 2020-10-22 (38)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322113; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-09-06 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3322132; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-15 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322167; Age (years): 52; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PERSISTENT SHOULDER PAIN ON SAME ARM AS INJECTION SITE (LEFT)	2020-09-01 18:30 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322173; Age (years): 48; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-18 (49)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3322252; Age (years): 37; Sex: F; Race: ASIAN							
Injury, poisoning and procedural complications/ Ligament sprain/ LEFT SACROILIAC JOINT STRAIN, ACUTE	2020-11-02 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322252; Age (years): 37; Sex: F; Race: ASIAN							
Nervous system disorders/ Sciatica/ LUMBAGO WITH RADICULOPATHY, ACUTE	2020-11-02 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322302; Age (years): 37; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Wrist fracture/ RIGHT SCAPHOID FRACTURE	2020-10-22 (15)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322308; Age (years): 28; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ DELAYED SITE INJECTION REACTION (RASH) OF LEFT UPPER EXTREMITY	2020-09-20 (9)/ 2020-09-22 (11)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322312; Age (years): 59; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ NEWLY DIAGNOSED DIABETES MELLITUS TYPE 2	2020-09-25 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-25 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322319; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS, ACUTE	2020-10-13 (6)/ 2020-10-19 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322324; Age (years): 29; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-10-28 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322324; Age (years): 29; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-28 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3322329; Age (years): 51; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling face/ FACIAL SWELLING	2020-10-17 (3)/ 2020-10-22 (8)	Yes/ Yes/ No	3	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3322353; Age (years): 73; Sex: M; Race: WHITE							
Renal and urinary disorders/ Lower urinary tract symptoms/ LOWER URINARY TRACT SYMPTOMS	2020-09-29 (15)/ 2020-10-02 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322353; Age (years): 73; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE ADENOCARCINOMA	2020-10-16 (4)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-11-03 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3322408; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-12 (11)/ 2020-10-19 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3322408; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-12 (11)/ 2020-10-19 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332002; Age (years): 66; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LEFT PINKY FINGER LACERATION	2020-08-17 (14)/ 2020-09-01 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ WORSENING OF RIGHT FOOT PAIN	2020-10-06 (33)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332003; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF RIGHT KNEE PAIN	2020-08-11 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-09-02 (30)/ 2020-09-10 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332015; Age (years): 65; Sex: F; Race: WHITE							
Cardiac disorders/ Palpitations/ INCREASED DURATION OF HEART PALPITATIONS	2020-09-14 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3332020; Age (years): 35; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-06 (27)/ 2020-10-08 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332020; Age (years): 35; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-06 (27)/ 2020-10-08 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-06 (27)/ 2020-10-08 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-06 (27)/ 2020-10-08 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332020; Age (years): 35; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-06 (27)/ 2020-10-08 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3332033; Age (years): 77; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-11 08:06 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3332046; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-19 (12)/ 2020-09-30 (23)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332061; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Conjunctivitis/ BILATERAL CONJUNCTIVITIS	2020-10-09 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332074; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-11-17 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3332076; Age (years): 45; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Hand fracture/ LEFT HAND FRACTURE	2020-09-08 (7)/ 2020-10-30 (59)	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3332089; Age (years): 42; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-09-18 21:46 (2)/ 2020-10-09 08:00 (22)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3332099; Age (years): 51; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-11-17 (8)/ 2020-11-24 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3342009; Age (years): 68; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Epicondylitis/ LEFT LATERAL EPICONDYLITIS	2020-08-20 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ RHINITIS ALLERGENIC	2020-09-21 (12)/ 2020-09-22 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342021; Age (years): 39; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Gluten sensitivity/ ABDOMINAL PAIN DUE TO SUSPECTED GLUTEN ALLERGY	2020-09-27 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Gastroenteritis/ INFECTIOUS GASTROENTERITIS AND COLITIS UNSPECIFIED	2020-09-27 (14)/ 2020-10-01 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342028; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-21 (14)/ 2020-09-26 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342033; Age (years): 46; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Meniscus cyst/ RIGHT MENISCAL CYST BENIGN	2020-08-26 (15)/ 2020-09-01 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: RIGHT MENISCAL CYST
Subject ID: US3342055; Age (years): 32; Sex: F; Race: WHITE							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-09-23 (9)/ 2020-10-03 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342063; Age (years): 46; Sex: F; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Arthralgia/ POLYARTHRALGIA	2020-09-13 (31)/ 2020-09-21 (39)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Malaise/ GENERALIZED MALAISE	2020-09-15 02:30 (1)/ 2020-10-02 18:00 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342063; Age (years): 46; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Malaise/ WORSENING OF GENERALIZED MALAISE	2020-09-21 (8)/ 2020-10-02 (19)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF POLYARTHRALGIA	2020-09-21 (8)/ 2020-10-02 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342068; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Viral upper respiratory tract infection/ UPPER RESPIRATORY INFECTION VIRAL	2020-11-14 (61)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342070; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Gingivitis/ ACUTE GINGIVITIS	2020-09-25 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3342071; Age (years): 40; Sex: F; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT HYPERACTIVITY DISORDER.	2020-10-27 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342076; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Gingivitis/ ACUTE GINGIVITIS	2020-09-25 (10)/ 2020-10-05 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342098; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ Soft tissue infection/ SOFT TISSUE INFECTION OF LEFT FOOT FIRST DIGIT	2020-08-26 (9)/ 2020-09-04 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342099; Age (years): 67; Sex: F; Race: WHITE							
Eye disorders/ Conjunctivitis allergic/ ALLERGIC CONJUNCTIVITIS LEFT EYE	2020-09-19 (33)/ 2020-09-23 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342120; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-05 (15)/ 2020-10-13 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342129; Age (years): 58; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Musculoskeletal and connective tissue disorders/ Back pain/ TRAUMATIC FALL RESULTING IN MUSCULAR BACK PAIN	2020-10-28 (38)/ 2020-10-28 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342136; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Trigger finger/ TRIGGER FINGER L 4TH DIGIT	2020-09-10 (22)/ 2020-09-11 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Trigger finger/ TRIGGER FINGER R 4TH DIGIT	2020-09-10 (22)/ 2020-09-11 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Limb injury/ RIGHT SHOULDER INJURY SECONDARY TO FALL OFF BICYCLE	2020-10-02 (9)/ 2020-10-31 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342141; Age (years): 69; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-04 (15)/ 2020-09-21 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342143; Age (years): 33; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-10-01 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Hiatus hernia/ HIATAL HERNIA	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342150; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Conjunctivitis/ BILATERAL CONJUNCTIVITIS	2020-09-10 (14)/ 2020-09-17 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342154; Age (years): 39; Sex: F; Race: WHITE							
Eye disorders/ Orbital haematoma/ LEFT ORBITAL HEMATOMA	2020-11-08 (38)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3342167; Age (years): 24; Sex: M; Race: WHITE							
Nervous system disorders/ Presyncope/ VASOVAGAL REACTION	2020-09-01 16:55 (1)/ 2020-09-01 17:32 (1)	Yes/ Yes/ No	1	No	NR/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342172; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ VIRAL SINUS INFECTION	2020-11-02 (33)/ 2020-11-18 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342203; Age (years): 74; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS	2020-11-01 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342205; Age (years): 29; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection bacterial/ UPPER RESPIRATORY INFECTION BACTERIAL	2020-09-15 (8)/ 2020-10-05 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-09-24 (17)/ 2020-09-29 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342208; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT LOWER EXTREMITY PAIN	2020-11-15 (35)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342208; Age (years): 66; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-11-20 (40)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3342239; Age (years): 30; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Head injury/ HEAD TRAUMA	2020-10-13 (34)/ Ongoing	Yes/ Yes/ No	1	No	NR/ R	DRUG WITHDRAWN/ NONE	RECOVERING/ RESOLVING
Subject ID: US3342255; Age (years): 36; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS	2020-10-01 (21)/ 2020-10-02 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3342268; Age (years): 46; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ RIGHT SHOULDER STRAIN	2020-09-17 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342268; Age (years): 46; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ MUSCLE STRAIN RIGHT CALF	2020-09-22 (8)/ 2020-10-29 (45)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Limb injury/ INJURY TO L SHOULDER.	2020-10-22 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3342272; Age (years): 57; Sex: M; Race: WHITE							
Vascular disorders/ Haematoma/ HEMATOMA RIGHT ANTECUBITAL	2020-09-18 17:00 (1)/ 2020-09-28 00:00 (10)	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342274; Age (years): 61; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Vaginal discharge/ LEUKORRHEA, NONINFECTIVE	2020-10-12 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342274; Age (years): 61; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ RIGHT SHOULDER INJURY EXACERBATION	2020-10-26 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3342281; Age (years): 42; Sex: M; Race: OTHER: (b) (6)							
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION	2020-10-27 04:30 (33)/ 2020-11-20 10:00 (57)	Yes/ Yes/ No	2	Yes/3 (2020-10-29/ 2020-10-30)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3342288; Age (years): 46; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Tooth impacted/ WISDOM TOOTH IMPACTION	2020-10-20 (25)/ 2020-11-04 (40)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3342302; Age (years): 32; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ LUMBAGO	2020-10-28 (3)/ 2020-10-29 (4)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352109; Age (years): 77; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ MIGRAINES	2020-09-26 (10)/ 2020-09-30 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352114; Age (years): 61; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Temporomandibular joint syndrome/ TEMPOROMANDIBULAR JOINT DYSFUNCTION	2020-09-15 (29)/ 2020-10-26 (70)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352250; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-18 (25)/ 2020-09-28 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352288; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ Cellulitis/ LEFT LEG CELLULITIS	2020-11-11 (51)/ 2020-11-18 (58)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3352299; Age (years): 48; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash vesicular/ DISSEMINATED VESICULAR RASH ALL OVER BODY	2020-11-08 (41)/ 2020-11-13 (46)	Yes/ Yes/ No	4	Yes/3 (2020-11-08/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ RASH SKIN ERUPTION	2020-11-11 (44)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352299; Age (years): 48; Sex: M; Race: WHITE							
Investigations/ Transaminases increased/ ELEVATED TRANSAMINASE LEVEL	2020-11-11 (44)/ 2020-11-13 (46)	Yes/ Yes/ No	4	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352301; Age (years): 63; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ MOLAR PAIN	2020-11-14 (45)/ 2020-11-14 (45)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352491; Age (years): 50; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-16 (11)/ 2020-10-24 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-16 (11)/ 2020-10-30 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3352491; Age (years): 50; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-16 (11)/ 2020-10-30 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3352594; Age (years): 31; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ SITUATIONAL ANXIETY	2020-10-22 18:00 (1)/ 2020-10-23 00:00 (1)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES ALL OVER BODY	2020-10-22 18:00 (1)/ 2020-10-25 (4)	Yes/ Yes/ No	3	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362002; Age (years): 46; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-02 (3)/ 2020-08-02 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362002; Age (years): 46; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-02 (3)/ 2020-08-02 (3)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-28 (32)/ 2020-10-02 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362014; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 (49)/ 2020-10-20 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362016; Age (years): 45; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Cartilage injury/ LABRUM TEAR	2020-08-27 (25)/ 2020-08-27 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362023; Age (years): 55; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Swollen tongue/ TONGUE SWELLING - POST INJECTION ALLERGIC REACTION	2020-08-03 16:20 (1)/ 2020-08-03 18:20 (1)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362032; Age (years): 61; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA WITH ACUTE EXACERBATION DUE TO INHALATION OF CHEMICAL	2020-09-16 (13)/ 2020-09-16 (13)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362034; Age (years): 50; Sex: M; Race: WHITE							
Eye disorders/ Retinal detachment/ RETINAL DETACHMENT OF LEFT EYE	2020-11-06 (60)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362056; Age (years): 21; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP PHARYNGITIS	2020-08-23 (19)/ 2020-08-25 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362057; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ Injection site cellulitis/ (INJECTION SITE) EOSINOPHILIC CELLULITIS, LEFT UPPER ARM	2020-08-13 (8)/ 2020-08-17 (12)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362060; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP PHARYNGITIS	2020-09-11 (9)/ 2020-09-17 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362060; Age (years): 24; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LEFT THUMB LACERATION	2020-09-22 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362077; Age (years): 49; Sex: F; Race: WHITE							
Investigations/ Influenza A virus test positive/ INFLUENZA A POSITIVE	2020-10-05 (25)/ 2020-10-07 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Dacryocystitis/ DACRYOCYSTITIS	2020-10-26 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3362088; Age (years): 41; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREPTOCOCCAL PHARYNGITIS	2020-10-28 (47)/ 2020-11-06 (56)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362092; Age (years): 65; Sex: F; Race: WHITE							
Investigations/ Glycosylated haemoglobin increased/ ELEVATED A1C	2020-10-10 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3362097; Age (years): 53; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Diabetes mellitus/ WORSENING DIABETES MELLITUS	2020-09-08 20:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Hypertension/ HYPERTENSIVE EPISODE	2020-10-07 (30)/ 2020-10-08 (31)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362103; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-09-02 (24)/ 2020-09-11 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362107; Age (years): 27; Sex: M; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID 19 SYMPTOMS	2020-11-04 (58)/ 2020-11-07 (61)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362115; Age (years): 28; Sex: F; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT HYPERACTIVITY DISORDER	2020-10-28 (49)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3362116; Age (years): 56; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ LOWER BACK MUSCLE STRAIN	2020-08-31 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-19 04:30 (1)/ 2020-09-20 10:00 (2)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362116; Age (years): 56; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MYALGIAS	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Neck pain/ WORSENING OF CHRONIC NECK PAIN	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-19 04:30 (1)/ 2020-09-21 08:00 (3)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362121; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-22 (13)/ 2020-10-01 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362124; Age (years): 20; Sex: M; Race: UNKNOWN							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID 19	2020-08-18 (6)/ 2020-09-18 (37)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362128; Age (years): 62; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-08-15 (3)/ 2020-08-19 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362148; Age (years): 21; Sex: F; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ SUSPECTED COVID 19	2020-11-06 (45)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3362157; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-09-18 (4)/ 2020-09-28 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362157; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-11-03 (50)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362160; Age (years): 22; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL LEFT SUPRACLAVICULAR LYMPH NODE SWELLING	2020-08-22 (8)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3362164; Age (years): 21; Sex: M; Race: ASIAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-28 (11)/ 2020-10-02 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-28 (11)/ 2020-10-02 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362164; Age (years): 21; Sex: M; Race: ASIAN							
Gastrointestinal disorders/ Vomiting/ VOMITING	2020-09-28 (11)/ 2020-10-02 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-28 (11)/ 2020-10-02 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362177; Age (years): 65; Sex: M; Race: WHITE							
Renal and urinary disorders/ Haematuria/ HEMATURIA	2020-09-28 (14)/ 2020-10-05 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362182; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Carotid artery stenosis/ RIGHT CAROTID STENOSIS 50%	2020-09-28 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362204; Age (years): 57; Sex: F; Race: MULTIPLE:				(b) (6)			
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-08-30 (11)/ 2020-08-31 (12)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362207; Age (years): 67; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Ingrowing nail/ RIGHT INGROWN TOENAIL	2020-08-25 (6)/ 2020-09-03 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3362215; Age (years): 35; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Insulin resistance/ INSULIN RESISTANT	2020-10-08 (49)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362222; Age (years): 51; Sex: F; Race: WHITE							
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2020-10-09 (8)/ 2020-10-11 (10)	Yes/ Yes/ No	4	Yes/3 (2020-10-10/ 2020-10-11)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362223; Age (years): 66; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-09-22 (1)/ 2020-09-29 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-10 (50)/ 2020-11-21 (61)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362244; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF LEFT HIP PAIN/ARTHRITIS	2020-09-08 (16)/ 2020-11-11 (80)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362244; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Fracture nonunion/ WORSENING OF ANTERIOR LEFT PELVIC RING NON-UNION	2020-09-09 (17)/ 2020-10-05 (43)	Yes/ Yes/ No	4	Yes/3 (2020-09-29/ 2020-10-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Postoperative abscess/ POST OPERATIVE INTRA-ABDOMINAL ABSCESS	2020-10-12 (50)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-12/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Vascular disorders/ Axillary vein thrombosis/ RIGHT AXILLARY DEEP VEIN THROMBOSIS	2020-10-19 (57)/ Ongoing	Yes/ Yes/ No	4	Yes/2	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362244; Age (years): 66; Sex: F; Race: WHITE							
Vascular disorders/ Deep vein thrombosis/ RIGHT BRACHIAL DEEP VEIN THROMBOSIS	2020-10-19 (57)/ Ongoing	Yes/ Yes/ No	4	Yes/2	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-29 (67)/ 2020-11-12 (81)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3362245; Age (years): 68; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma of skin/ SQUAMOUS CELL CARCINOMA OF SCALP	2020-10-02 (12)/ 2020-10-30 (40)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362245; Age (years): 68; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Insulin resistance/ WORSENING OF INSULIN RESISTANCE	2020-10-12 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Postoperative wound infection/ INFECTION OF SCALP INCISION	2020-11-04 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362257; Age (years): 67; Sex: F; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA RIGHT UPPER LOBE	2020-09-21 (27)/ 2020-09-30 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362269; Age (years): 49; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-05 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3362271; Age (years): 52; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-08 (9)/ 2020-10-19 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362277; Age (years): 39; Sex: M; Race: WHITE							
Immune system disorders/ Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2020-10-16 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3362280; Age (years): 57; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIAL RASH TO GROIN	2020-10-09 (3)/ 2020-10-23 (17)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3362284; Age (years): 53; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORREA	2020-10-09 (25)/ 2020-10-19 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362285; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Cerebrovascular accident/ CEREBROVASCULAR ACCIDENT	2020-11-16 (26)/ 2020-11-18 (28)	Yes/ Yes/ No	4	Yes/2/3 (2020-11-16/ 2020-11-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3362303; Age (years): 53; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-10-10 (5)/ 2020-10-19 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372013; Age (years): 59; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-10-21 (52)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372041; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-23 (20)/ 2020-09-28 (25)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372049; Age (years): 62; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-21 (19)/ 2020-10-06 (34)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372123; Age (years): 57; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Cervical spinal stenosis/ CERVICAL STENOSIS	2020-11-02 (50)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Chronic kidney disease/ CHRONIC KIDNEY DISEASE	2020-11-02 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372135; Age (years): 69; Sex: F; Race: WHITE							
Endocrine disorders/ Hypothyroidism/ HYPOTHYROIDISM	2020-10-29 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372151; Age (years): 58; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ BILATERAL LOWER EXTREMITY MUSCLE PAIN	2020-10-23 (38)/ 2020-10-25 (40)	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372154; Age (years): 69; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Burns first degree/ FIRST DEGREE BURN-FACE	2020-09-12 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372161; Age (years): 78; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ URTICARIA - INSECT BITE LEFT LATERAL UPPER ARM	2020-10-05 (19)/ 2020-10-07 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372235; Age (years): 61; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL CARCINOMA LEFT INNER THIGH	2020-09-03 (10)/ 2020-09-03 (10)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3372240; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Staphylococcal infection/ MRSA	2020-09-08 (15)/ 2020-09-19 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Subcutaneous abscess/ ABSCESS LUMBAR LEFT SIDE	2020-09-08 (15)/ 2020-09-23 (30)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372276; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Sialoadenitis/ SIALADENITIS	2020-09-02 (7)/ 2020-09-16 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372281; Age (years): 71; Sex: F; Race: WHITE							
Infections and infestations/ Conjunctivitis/ CONJUNCTIVITIS RIGHT EYE	2020-08-31 (4)/ 2020-09-04 (8)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3372345; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ Infected bite/ DOG BITE FOREHEAD INFECTED	2020-10-15 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372370; Age (years): 59; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-03 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372380; Age (years): 71; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ SPRAIN OF LEFT SHOULDER	2020-11-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372380; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN IN THE RIGHT THUMB	2020-11-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372394; Age (years): 68; Sex: F; Race: WHITE							
Vascular disorders/ Arteriosclerosis/ SYMPTOMATIC ATHEROSCLEROTIC DISEASE.	2020-11-11 (34)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-11/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372398; Age (years): 74; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Bursitis/ BURSITIS RIGHT ELBOW	2020-11-04 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3372447; Age (years): 46; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-05 (14)/ 2020-10-08 (17)	Yes/ Yes/ Yes	1	No	R/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3372487; Age (years): 37; Sex: F; Race: ASIAN							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-11-11 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382021; Age (years): 40; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-10-26 (47)/ 2020-10-29 (50)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382036; Age (years): 32; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod sting/ HORNET STING	2020-09-11 (1)/ 2020-09-12 (2)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382048; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Joint swelling/ JOINT SWELLING	2020-10-07 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382062; Age (years): 73; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMATOUS PLAQUES ON SKIN	2020-09-03 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382103; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ HERPES ZOSTER - LEFT SIDE	2020-09-14 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382107; Age (years): 29; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injury associated with device/ ACCIDENTAL NEEDLE STICK	2020-09-19 (26)/ 2020-09-19 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382109; Age (years): 43; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-30 (7)/ 2020-10-05 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Anosmia/ LOSS OF SMELL	2020-09-30 (7)/ 2020-10-09 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-30 (7)/ 2020-10-09 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-30 (7)/ 2020-10-09 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382109; Age (years): 43; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-10-01 (8)/ 2020-10-04 (11)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-01 (8)/ 2020-10-05 (12)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-01 (8)/ 2020-10-05 (12)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382109; Age (years): 43; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-02 (9)/ 2020-10-05 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (9)/ 2020-10-06 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-02 (9)/ 2020-10-06 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382120; Age (years): 22; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Lumbar vertebral fracture/ FRACTURE OF A LUMBAR VERTEBRA	2020-10-07 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382168; Age (years): 25; Sex: F; Race: WHITE							
Infections and infestations/ Chlamydial infection/ CHLAMYDIA INFECTION	2020-10-01 00:00 (1)/ 2020-10-08 14:00 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382194; Age (years): 31; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus pain/ SINUS PAIN	2020-10-03 (31)/ 2020-10-14 (42)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3382209; Age (years): 46; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-06 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382225; Age (years): 36; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA - RIGHT FOREHEAD	2020-10-02 (24)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382234; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-20 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382235; Age (years): 43; Sex: F; Race: WHITE							
Product issues/ Embedded device/ EMBEDDED INTRAUTERINE DEVICE	2020-09-23 (14)/ 2020-09-29 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Ear infection/ EAR INFECTION	2020-10-04 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382239; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Hordeolum/ HORDEOLUM EXTERNAL- LEFT LOWER EYE LID	2020-09-27 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-02 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382267; Age (years): 49; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ GENERALIZED RASH	2020-10-13 (2)/ Ongoing	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3382271; Age (years): 72; Sex: F; Race: ASIAN							
Infections and infestations/ Otitis externa/ LEFT EXTERNAL EAR INFECTION	2020-11-01 00:00 (18)/ 2020-11-09 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3382271; Age (years): 72; Sex: F; Race: ASIAN							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-11-04 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Facial paralysis/ BELL'S PALSY	2020-11-04 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3382284; Age (years): 45; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Gastric cancer/ GASTRIC CANCER	2020-10-29 (44)/ Ongoing	Yes/ Yes/ No	3	Yes/2/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3392004; Age (years): 62; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	2020-11-16 (69)/ 2020-11-16 (69)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Hypoaesthesia/ NUMBNESS, FACIAL	2020-11-16 (69)/ 2020-11-16 (69)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Presyncope/ PRE-SYNCOPE	2020-11-18 (71)/ 2020-11-18 (71)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3392025; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-10-25 (48)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3392112; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-17 (26)/ 2020-10-22 (31)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3392120; Age (years): 63; Sex: M; Race: WHITE							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-24 (25)/ 2020-10-26 (27)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3392149; Age (years): 30; Sex: M; Race: WHITE							
Infections and infestations/ Hepatitis A/ HEPATITIS A	2020-09-24 (23)/ 2020-09-25 (24)	Yes/ Yes/ No	3	Yes/3 (2020-09-24/ 2020-09-25)	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3392236; Age (years): 48; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pleurisy/ PLEURISY	2020-10-13 (7)/ 2020-10-16 (10)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3392258; Age (years): 55; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ FOOT FRACTURE	2020-10-09 12:00 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3392296; Age (years): 47; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Breast cancer in situ/ IN SITU CARCINOMA, BREAST	2020-11-09 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402010; Age (years): 25; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT SPRAINED ANKLE	2020-08-09 (14)/ 2020-08-17 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3402012; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Conjunctivitis/ DOUBLE PINK EYE	2020-09-08 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3402042; Age (years): 72; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Emphysema/ WORSENING OF EMPHYSEMA	2020-10-01 (38)/ 2020-10-17 (54)	Yes/ Yes/ No	2	Yes/3 (2020-10-13/ 2020-10-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402079; Age (years): 72; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperkalaemia/ MILD HYPERKALEMIA	2020-09-28 (32)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402083; Age (years): 48; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Inguinal hernia/ INGUINAL HERNIA	2020-09-18 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3402098; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ Dermatophytosis of nail/ TINEA UNQUIUM	2020-09-16 (21)/ 2020-09-16 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402129; Age (years): 38; Sex: M; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES RIGHT SIDE OF CHEST	2020-08-18 (18)/ 2020-08-25 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402135; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ RHINOSINUSITIS	2020-08-16 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-08-16 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402139; Age (years): 55; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING LEFT KNEE ARTHRITIS	2020-08-09 (9)/ 2020-10-14 (75)	Yes/ Yes/ No	2	Yes/3 (2020-10-12/ 2020-10-14)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT UNDERGOING PHYSICAL THERAPY

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402171; Age (years): 68; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ SPRAINED LEFT KNEE	2020-08-16 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402212; Age (years): 79; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ WORSENING SPINAL STENOSIS	2020-08-23 (20)/ 2020-09-29 (57)	Yes/ Yes/ No	3	Yes/3 (2020-08-23/ 2020-08-25)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3402233; Age (years): 66; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Gout/ WORSENING OF RIGHT FOOT GOUT	2020-10-05 (34)/ Ongoing	Yes/ Yes/ No	2	No	NA/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3402242; Age (years): 58; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ankle fracture/ RIGHT ANKLE FRACTURE	2020-10-26 (48)/ 2020-10-27 (49)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402255; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-08-13 (8)/ 2020-08-20 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3402282; Age (years): 37; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-08-18 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS IN BACK	2020-10-13 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402284; Age (years): 58; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-09-22 (13)/ 2020-09-23 (14)	Yes/ Yes/ No	3	Yes/3 (2020-09-22/ 2020-09-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402316; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-09 (32)/ 2020-09-16 (39)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-10-12 (32)/ 2020-10-26 (46)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Pregnancy, puerperium and perinatal conditions/ Pregnancy/ PREGNANCY	2020-10-24 (44)/ Ongoing	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402319; Age (years): 30; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Scar/ SCAR TISSUE ON LEFT FOOT	2020-09-24 (14)/ 2020-09-24 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: STILL TAKING ANTIBIOTICS

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402319; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTED LEFT FOOT	2020-10-09 (29)/ 2020-10-21 (41)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3402324; Age (years): 38; Sex: F; Race: WHITE							
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2020-11-02 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402343; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Papilloma viral infection/ HUMAN PAPILLOMAVIRUS INFECTION	2020-11-04 (50)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402346; Age (years): 41; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ DEPRESSION	2020-09-01 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402353; Age (years): 47; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-11 23:12 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3402354; Age (years): 69; Sex: M; Race: WHITE							
Renal and urinary disorders/ Cystitis interstitial/ INTERSTITIAL CYSTITIS OF THE BLADDER	2020-10-01 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402360; Age (years): 38; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-01 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Skin and subcutaneous tissue disorders/ Hand dermatitis/ LEFT INDEX FINGER DERMATITIS	2020-09-11 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402367; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-04 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402376; Age (years): 38; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ SWOLLEN LYMPH NODES LEFT AXILLA	2020-08-30 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2020-10-24 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3402380; Age (years): 24; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Helicobacter infection/ H.PYLORI INFECTION OF THE STOMACH	2020-09-04 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3402416; Age (years): 46; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ FRACTURED 5TH METATARSAL LEFT FOOT	2020-10-11 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3402418; Age (years): 55; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteopenia/ OSTEOPENIA	2020-09-18 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3402462; Age (years): 56; Sex: M; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTED RIGHT INDEX FINGER	2020-11-13 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412009; Age (years): 70; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ URI	2020-11-18 (85)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	
Subject ID: US3412013; Age (years): 58; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ CATBITE	2020-11-20 (87)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-22/)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3412019; Age (years): 68; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Fall/ MECHANICAL FALL	2020-09-16 (22)/ 2020-09-16 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	2020-09-20 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412053; Age (years): 28; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING ANXIETY	2020-08-15 (17)/ 2020-09-15 (48)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412056; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Acute sinusitis/ ACUTE SINUSITIS	2020-08-19 (20)/ 2020-08-23 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Otitis media acute/ ACUTE OTITIS MEDIA	2020-08-19 (20)/ 2020-08-23 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3412069; Age (years): 33; Sex: F; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2020-09-09 (13)/ 2020-09-09 (13)	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412091; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ Acute sinusitis/ ACUTE SINUSITIS	2020-08-24 (19)/ 2020-08-25 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3412096; Age (years): 61; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-08-23 (18)/ 2020-08-29 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412113; Age (years): 55; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Wrist fracture/ FRACTURE (CLOSED) (LEFT WRIST)	2020-08-31 (1)/ 2020-09-21 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3412124; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ CERVICAL STRAIN	2020-08-23 (20)/ 2020-08-25 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412125; Age (years): 71; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Blood loss anaemia/ ACUTE POST HEMORRHAGIC ANEMIA	2020-09-08 (8)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT	2020-09-08 (8)/ 2020-09-08 (8)	Yes/ Yes/ No	4	Yes/2/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Cervical vertebral fracture/ CERVICAL 7 FRACTURE	2020-09-09 (9)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Rib fracture/ NONDISPLACED RIB FRACTURES RIGHT 1-2	2020-09-09 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412125; Age (years): 71; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Traumatic liver injury/ GRADE IV LIVER LACERATION	2020-09-09 (9)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	UNKNOWN
Nervous system disorders/ Embolic stroke/ MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT	2020-09-09 (9)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Infections and infestations/ Pneumonia staphylococcal/ MRSA PNEUMONIA	2020-09-09 (9)/ 2020-09-29 (29)	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Coronary artery thrombosis/ LEFT INTERCAROTID ARTERY DISSECTION WITH INTRALUMINAL THROMBUS	2020-09-13 (13)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN

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Subject ID: US3412125; Age (years): 71; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Lower limb fracture/ RIGHT TIB/ FIB FRACTURE	2020-09-13 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	UNKNOWN
Metabolism and nutrition disorders/ Hyperglycaemia/ HRYPEGLYCEMUA	2020-09-13 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	2020-09-13 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	UNKNOWN
Cardiac disorders/ Acute myocardial infarction/ NON STEMI VS CARDIAC CONTUSION	2020-09-13 (13)/ 2020-10-01 (31)	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412125; Age (years): 71; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Craniocerebral injury/ TRAUMATIC BRAIN INJURY	2020-09-23 (23)/ 2020-10-01 (31)	Yes/ Yes/ No	4	Yes/3 (2020-09-08/ 2020-10-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: FUNCTION OF SUBJECT CONFUSION, WEAKNESS
Subject ID: US3412126; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-08-05 (2)/ 2020-08-18 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ RIB PAIN	2020-08-23 (20)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412126; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-08-23 (20)/ 2020-11-14 (103)	Yes/ Yes/ No	4	Yes/3 (2020-08-23/ 2020-09-01)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3412129; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-08-12 (8)/ 2020-09-13 (40)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412135; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-08-16 (12)/ 2020-08-24 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412143; Age (years): 20; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY - (WORSENING)	2020-10-28 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412143; Age (years): 20; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS - MILD SHORTNESS OF BREATH, MILD CONGESTION, MILD SORE THROAT, MILD HEADACHES.	2020-11-09 (50)/ 2020-11-15 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412147; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Acute sinusitis/ ACUTE SINITUS	2020-08-25 (21)/ 2020-09-12 (39)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412153; Age (years): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ CHRONIC HYPERTENSION WORSENING	2020-09-24 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412167; Age (years): 37; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS DUE POISON IVY - SMALL AREA ON FOREHEAD.	2020-10-04 (25)/ 2020-10-12 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412231; Age (years): 31; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ CHRONIC LOWER BACK PAIN - EXACERBATION	2020-10-07 (28)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3412236; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS - RESPIRATORY INFECTION	2020-09-07 (26)/ 2020-09-17 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412252; Age (years): 76; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ DENTAL ABSCESS	2020-08-17 (4)/ 2020-09-01 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412283; Age (years): 40; Sex: M; Race: WHITE							
Infections and infestations/ Conjunctivitis/ BILATERAL CONJUNCTIVITIS	2020-11-04 (49)/ 2020-11-11 (56)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412286; Age (years): 73; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-09-18 (2)/ 2020-10-04 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412323; Age (years): 62; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ CHRONIC LOWBACK PAIN WORSENING FROM BASELINE HNP L4 / L5	2020-09-30 (9)/ 2020-10-24 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3412350; Age (years): 62; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Trigger finger/ RIGHT 4TH DIGIT TRIGGER FINGER.	2020-09-07 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3412353; Age (years): 37; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-10-08 (9)/ 2020-10-10 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3412362; Age (years): 64; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Upper limb fracture/ RIGHT ARM FRACTURED AT THE ELBOW	2020-10-05 (5)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3412383; Age (years): 64; Sex: M; Race: ASIAN							
Gastrointestinal disorders/ Toothache/ WORSENING TOOTH PAIN	2020-11-01 (12)/ 2020-11-11 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422051; Age (years): 54; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ FINGER LACERATION	2020-09-16 (3)/ 2020-09-16 (3)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422069; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Animal scratch/ CAT SCRATCHES- MULTIPLE	2020-09-25 (11)/ 2020-10-04 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422077; Age (years): 24; Sex: M; Race: WHITE							
Nervous system disorders/ Cubital tunnel syndrome/ CUBITAL TUNNEL SYNDROME	2020-09-17 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3422086; Age (years): 35; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament rupture/ RIGHT TORN MEDIAL COLLATERAL LIGAMENT	2020-09-29 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422093; Age (years): 76; Sex: M; Race: WHITE							
Nervous system disorders/ Paraesthesia/ RIGHT UPPER EXTREMITY PARESTHESIA	2020-10-13 (23)/ 2020-10-19 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422101; Age (years): 35; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREPTOCOCCAL PHARYNGITIS	2020-11-16 (56)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3422111; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Subcutaneous abscess/ SKIN ABSCESS RIGHT AXILLA	2020-09-30 (8)/ 2020-10-10 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422119; Age (years): 24; Sex: M; Race: WHITE							
Infections and infestations/ Sexually transmitted disease/ SEXUALLY TRANSMITTED INFECTION	2020-10-08 (14)/ 2020-10-09 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3422122; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-09-08 (13)/ 2020-09-22 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422127; Age (years): 40; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ OSTEOARTHRITIS IN LOWER BACK	2020-10-03 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422135; Age (years): 67; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ SPINAL STENOSIS	2020-10-06 (12)/ 2020-10-08 (14)	Yes/ Yes/ No	3	Yes/3 (2020-10-06/ 2020-10-08)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422151; Age (years): 65; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-04 (7)/ 2020-10-07 (10)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3422167; Age (years): 33; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ R ELBOW LACERATION	2020-10-27 (22)/ 2020-10-27 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3422167; Age (years): 33; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-10-29 (24)/ 2020-11-02 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3422182; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Rocky mountain spotted fever/ ROCKY MOUNTAIN SPOTTED FEVER	2020-10-27 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3422216; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ KNEE PAIN	2020-10-06 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3422236; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Traumatic fracture/ BONE FRACTURE (SPINE AND RIB) POST FALL	2020-11-19 (45)/	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3422282; Age (years): 61; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Crying/ WEEPING OF RIGHT CALF	2020-11-04 (23)/ 2020-11-09 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432016; Age (years): 76; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GERD	2020-10-22 (51)/ 2020-10-24 (53)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432056; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-09 (2)/ 2020-10-07 (30)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Facial paralysis/ BELL'S PALSY	2020-10-06 (29)/	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432057; Age (years): 28; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPH NODE (1/2 CM)	2020-09-04 (1)/ 2020-10-02 (29)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-23 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432064; Age (years): 25; Sex: F; Race: ASIAN							
Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	2020-09-09 06:30 (1)/ 2020-09-09 10:40 (2)	Yes/ Yes/ No	4	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432083; Age (years): 24; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	2020-09-05 (20)/ 2020-09-08 (23)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-10-28 (45)/ 2020-10-31 (48)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432086; Age (years): 63; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Pelvic pain/ BACK/PELVIC PAIN	2020-08-29 (19)/ 2020-09-12 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Subject ID: US3432086; Age (years): 63; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-12 (35)/ 2020-10-15 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432094; Age (years): 76; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Meningioma/ PROGRESSION OF MENINGIOMA	2020-10-28 (49)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Meningioma/ CRANIOPLASTY AND CRANIECTOMY FOR MENINGIOMA	2020-11-23 (75)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-23/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3432096; Age (years): 63; Sex: M; Race: WHITE							
Nervous system disorders/ Anosmia/ ANOSMIA	2020-08-15 (5)/ 2020-08-28 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432123; Age (years): 25; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Pharyngitis streptococcal/ STREPTOCOCCAL PHARYNGITIS	2020-09-07 (26)/ 2020-09-11 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432136; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-09 (28)/ 2020-10-16 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3432176; Age (years): 51; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-01 (16)/ 2020-09-09 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432188; Age (years): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Injection site erythema/ LATE ONSET INJECTION SITE REACTION (REDNESS)	2020-08-28 (11)/ 2020-09-10 (24)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432192; Age (years): 49; Sex: M; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS	2020-09-02 (6)/ 2020-09-02 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3432192; Age (years): 49; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-10-08 (15)/ 2020-10-12 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432199; Age (years): 67; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ INSECT BITES	2020-09-06 (19)/ 2020-09-11 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432203; Age (years): 65; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH (R ARM, L HIP)	2020-09-23 (8)/ 2020-10-14 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-11-03 (49)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432204; Age (years): 69; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ FRACTURED TOE (LEFT FOOT)	2020-09-12 (5)/ 2020-09-26 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432219; Age (years): 42; Sex: M; Race: WHITE							
Nervous system disorders/ Migraine/ MIGRAINE	2020-09-20 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432229; Age (years): 24; Sex: F; Race: WHITE							
Psychiatric disorders/ Intentional self-injury/ SELF- INJURIOUS BEHAVIOR	2020-10-17 (30)/ 2020-10-30 (43)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-30)/6	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432241; Age (years): 71; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ TICK BITE	2020-10-18 (31)/ 2020-10-28 (41)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432242; Age (years): 70; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Chronic lymphocytic leukaemia/ CLL - CHRONIC LYMPHOCYTIC LEUKEMIA	2020-10-08 (18)/ Ongoing	Yes/ Yes/ No	2	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432245; Age (years): 40; Sex: M; Race: WHITE							
Renal and urinary disorders/ Renal pain/ KIDNEY PAIN	2020-09-04 (14)/ 2020-09-21 (31)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432250; Age (years): 66; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin lesion/ SKIN LESION	2020-11-09 (50)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432257; Age (years): 36; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Chills/ CHILLS	2020-08-31 (8)/ 2020-08-31 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432268; Age (years): 32; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ HERNIATED DISK	2020-08-26 (3)/ 2020-11-01 (70)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432272; Age (years): 54; Sex: M; Race: ASIAN							
Infections and infestations/ Herpes zoster/ HERPES ZOSTER	2020-10-11 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3432273; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-10-26 (36)/ 2020-11-03 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432282; Age (years): 69; Sex: F; Race: WHITE							
Eye disorders/ Vitreous floaters/ FLOATERS(OCULAR, LEFT)	2020-08-26 (2)/ 2020-08-26 (2)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Eye disorders/ Vitreous floaters/ FLOATER (OCULAR, RIGHT)	2020-09-09 (16)/ 2020-09-09 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432286; Age (years): 71; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ PAROXYSTIC ATRIAL FIBRILLATION	2020-08-27 (3)/ 2020-08-27 (3)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432288; Age (years): 70; Sex: M; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-09-22 (29)/ 2020-09-23 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432288; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ L SHOULDER ARTHRITIS	2020-09-29 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA	2020-10-26 (29)/ 2020-11-18 (52)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-11-18 (52)/ Ongoing	Yes/ Yes/ No	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432293; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS INFECTION	2020-10-08 (16)/ 2020-10-22 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432314; Age (years): 52; Sex: F; Race: UNKNOWN							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-15 (20)/ 2020-09-24 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432334; Age (years): 29; Sex: M; Race: WHITE							
Infections and infestations/ Asymptomatic COVID-19/ SARS-COV-2 INFECTION (ASYMPTOMATIC)	2020-09-16 (20)/ 2020-09-26 (30)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432369; Age (years): 69; Sex: M; Race: WHITE							
Eye disorders/ Keratitis/ RIGHT EYE KERATITIS	2020-09-30 (31)/ 2020-10-27 (58)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Investigations/ Blood pressure systolic increased/ ELEVATED SYSTOLIC BLOOD PRESSURE (143 MMHG)	2020-10-05 (1)/ 2020-11-02 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432392; Age (years): 68; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ BENIGN PROSTATIC HYPERPLASIA (BPH) S/P TRANSURETHRAL RESECTION OF THE PROSTATE (TURP)	2020-10-19 (21)/ 2020-10-20 (22)	Yes/ Yes/ No	3	Yes/3 (2020-10-19/ 2020-10-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432395; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LEG PAIN	2020-09-16 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-18 (50)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432411; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Pulpitis dental/ L LOWER MOLAR INFLAMMATION/PAIN	2020-11-09 (40)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432459; Age (years): 71; Sex: F; Race: WHITE							
Eye disorders/ Blepharitis/ LEFT EYE BLEPHARITIS	2020-11-20 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3432465; Age (years): 65; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH	2020-10-22 (17)/ 2020-10-22 (17)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH	2020-10-26 (21)/ 2020-10-26 (21)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432471; Age (years): 40; Sex: F; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Respiratory symptom/ UPPER RESPIRATORY SYNDROME	2020-11-21 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3432494; Age (years): 55; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL SYNDROME	2020-10-24 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3432516; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Corneal abrasion/ SUPERFICIAL CORNEAL ABRASION	2020-11-02 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432516; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Burns second degree/ SECOND DEGREE BURNS (FACE, R EAR, R HAND)	2020-11-02 (18)/ 2020-11-18 (34)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432519; Age (years): 38; Sex: M; Race: WHITE							
Infections and infestations/ Viral upper respiratory tract infection/ UPPER RESPIRATORY VIRAL SYNDROME	2020-10-12 (26)/ 2020-11-01 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432533; Age (years): 24; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN	2020-11-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432552; Age (years): 40; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Concussion/ CONCUSSIVE SYNDROME	2020-10-12 (20)/ 2020-10-19 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432557; Age (years): 23; Sex: M; Race: ASIAN							
Injury, poisoning and procedural complications/ Procedural dizziness/ LIGHTHEADEDNESS POST BLOOD DRAW	2020-09-25 13:53 (1)/ 2020-09-25 14:03 (1)	No/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3432565; Age (years): 34; Sex: F; Race: ASIAN							
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFICIENCY	2020-10-07 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION SYMPTOMS	2020-10-07 (12)/ 2020-10-16 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432577; Age (years): 28; Sex: F; Race: ASIAN							
Injury, poisoning and procedural complications/ Foreign body in respiratory tract/ FOREIGN BODY IN LEFT NASAL CAVITY	2020-11-01 (33)/ 2020-11-02 (34)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3432589; Age (years): 55; Sex: F; Race: OTHER: (b) (6)							
Investigations/ Blood pressure diastolic increased/ HIGH DIASTOLIC BLOOD PRESSURE	2020-11-05 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Investigations/ Blood pressure systolic increased/ HIGH SYSTOLIC BLOOD PRESSURE	2020-11-05 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432590; Age (years): 23; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-10 (5)/ 2020-10-16 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3432627; Age (years): 33; Sex: F; Race: MULTIPLE: (b) (6)							
Skin and subcutaneous tissue disorders/ Pruritus/ LEFT ARM PRURITUS	2020-10-21 12:20 (1)/ 2020-10-21 17:45 (1)	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Hernia/ HERNIA S/P LEFT INGUINAL HERNIA REPAIR	2020-11-23 (6)/ 2020-11-24 (7)	Yes/ Yes/ No	3	Yes/3 (2020-11-23/ 2020-11-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3432631; Age (years): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-29 (9)/ 2020-11-11 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3442002; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Iron deficiency/ IRON DEFICIENCY	2020-09-28 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3442027; Age (years): 65; Sex: M; Race: WHITE							
Cardiac disorders/ Palpitations/ HEART PALPITATIONS	2020-09-24 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Hepatobiliary disorders/ Hepatic mass/ LUMP ON LIVER	2020-11-17 (64)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442031; Age (years): 55; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT CALF PAIN	2020-11-01 (42)/ 2020-11-12 (53)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2020-11-03 (44)/ 2020-11-04 (45)	Yes/ Yes/ No	3	Yes/3 (2020-11-03/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Deep vein thrombosis/ DEEP VEIN THROMBOSIS (LEFT LEG)	2020-11-03 (44)/ 2020-11-04 (45)	Yes/ Yes/ No	3	Yes/3 (2020-11-03/ 2020-11-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chest pain/ CHEST PAIN	2020-11-04 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442031; Age (years): 55; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-11-04 (45)/ 2020-11-12 (53)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3442073; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-02 (11)/ 2020-10-10 (19)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3442087; Age (years): 43; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-19 (56)/ 2020-10-22 (59)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3442100; Age (years): 71; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Actinic keratosis/ ACITINIC KERATOSIS ON LEFT FOREARM	2020-09-16 (21)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442111; Age (years): 42; Sex: F; Race: ASIAN							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-10-20 (23)/ 2020-10-24 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3442113; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Appendicitis/ APPENDICITIS	2020-09-02 21:00 (2)/ 2020-09-04 10:51 (3)	Yes/ Yes/ No	3	Yes/3 (2020-09-03/ 2020-09-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3442122; Age (years): 56; Sex: F; Race: WHITE							
Eye disorders/ Eye discharge/ BILATERAL EYE DISCHARGE	2020-09-29 (2)/ 2020-10-05 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Eye disorders/ Eye irritation/ BILATERAL EYE IRRITATION	2020-09-29 (2)/ 2020-10-05 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442125; Age (years): 70; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pharyngeal erythema/ PHAYRNX ERYTHEMA	2020-09-21 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Upper-airway cough syndrome/ CLEAR POST NASAL DRIP	2020-09-21 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3442147; Age (years): 60; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OSTEOARTHRITIS BILATERAL KNEE	2020-11-02 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3442233; Age (years): 72; Sex: F; Race: MULTIPLE:					(b) (6)		
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION RIGHT HAND	2020-11-21 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3442248; Age (years): 50; Sex: F; Race: WHITE							
Nervous system disorders/ Migraine/ MIGRAINES	2020-11-11 (21)/ 2020-11-11 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452045; Age (years): 69; Sex: M; Race: WHITE							
Vascular disorders/ Hot flush/ HOT FLASHES	2020-08-05 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3452069; Age (years): 40; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Asthma/ WORSENING OF ASTHMA	2020-10-27 (63)/ 2020-11-05 (72)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452092; Age (years): 38; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Floating patella/ RIGHT KNEE LUXATED PATELLA	2020-08-04 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3452125; Age (years): 62; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Impaired gastric emptying/ GASTROPARESIS	2020-08-11 (9)/ 2020-08-26 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452127; Age (years): 42; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-07 (5)/ 2020-08-15 (13)	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ COVID-19/ COVID-19	2020-10-12 (43)/ 2020-10-17 (48)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3452183; Age (years): 60; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-09-18 (16)/ 2020-10-27 (55)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452224; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Injection site cellulitis/ MILD CELLULITUS AT INJECTION SITE. LEFT ARM	2020-08-06 (2)/ 2020-08-20 (16)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3452368; Age (years): 44; Sex: M; Race: ASIAN							
Nervous system disorders/ Paraesthesia/ PARASTHESIA OF LEFT ARM	2020-09-17 (2)/ Ongoing	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3462017; Age (years): 55; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ COPD EXACERBATION	2020-09-18 (18)/ 2020-09-22 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462017; Age (years): 55; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ COPD EXACERBATION	2020-10-22 (52)/ 2020-10-29 (59)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462031; Age (years): 21; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-13 (12)/ 2020-09-16 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462076; Age (years): 28; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT WRIST SPRAIN	2020-09-07 (4)/ 2020-09-22 (19)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462091; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-10-09 (32)/ 2020-10-14 (37)	Yes/ Yes/ No	4	Yes/3 (2020-10-09/ 2020-10-14)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3462101; Age (years): 45; Sex: M; Race: WHITE							
Nervous system disorders/ Transient ischaemic attack/ TRANSIENT ISCHEMIC ATTACK	2020-09-25 06:00 (15)/ 2020-09-25 18:00 (16)	Yes/ Yes/ No	4	Yes/3 (2020-09-25/ 2020-09-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462133; Age (years): 61; Sex: F; Race: WHITE							
Cardiac disorders/ Cardiac failure/ HEART FAILURE	2020-08-23 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Nervous system disorders/ Cerebrovascular accident/ RIGHT TEMPORAL CVA	2020-08-23 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3462133; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Seizure/ GENERALIZED SEIZURES	2020-08-23 (12)/ 2020-08-26 (15)	Yes/ Yes/ No	4	Yes/3 (2020-08-23/ 2020-08-26)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3462225; Age (years): 61; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ COPD EXACERBATION	2020-09-15 (29)/ 2020-09-23 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3462404; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Oral candidiasis/ ORAL CANDIDIASIS	2020-09-26 (26)/ 2020-10-01 (31)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472001; Age (years): 70; Sex: M; Race: WHITE							
Investigations/ Hepatitis B antibody positive/ POSITIVE HEPATITIS B ANTIBODY	2020-09-29 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3472009; Age (years): 63; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hypertriglyceridaemia/ HYPERTRIGLYCERIDEMIA	2020-10-20 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3472013; Age (years): 59; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Oesophagitis/ ESOPHAGEAL SWELLING	2020-09-21 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Atelectasis/ ATELECTASIS	2020-09-21 (20)/ 2020-09-24 (23)	Yes/ Yes/ No	4	Yes/3 (2020-09-21/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472035; Age (years): 55; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY (BILATERAL AXILLARY)	2020-10-04 (24)/ 2020-10-18 (38)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472038; Age (years): 48; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Back pain/ CHRONIC BACK PAIN EXACERBATION	2020-09-20 (7)/ 2020-09-25 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3472043; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-27 (13)/ 2020-09-29 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472046; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ CHRONIC BACK PAIN EXACERBATION	2020-09-29 (14)/ 2020-10-02 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3472048; Age (years): 42; Sex: F; Race: MULTIPLE: (b) (6)							
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION	2020-10-26 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3472053; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Lyme disease/ PRESUMED LYME DISEASE	2020-09-24 (9)/ 2020-10-09 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3472054; Age (years): 47; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ DYSPNEA ON EXERTION	2020-11-04 (21)/ 2020-11-05 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3472054; Age (years): 47; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ DRY COUGH	2020-11-04 (21)/ 2020-11-11 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3472089; Age (years): 48; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Stab wound/ PARTICIPANT WAS STABBED ON 11/09/2020	2020-11-09 (12)/ 2020-11-09 (12)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482017; Age (years): 71; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-09 (29)/ 2020-10-19 (39)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-03 (54)/ Ongoing	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482019; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-09-09 02:00 (1)/ 2020-09-09 15:00 (2)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482023; Age (years): 70; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	2020-11-04 (42)/ 2020-11-05 (43)	Yes/ Yes/ No	4	Yes/3 (2020-11-04/ 2020-11-05)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482032; Age (years): 68; Sex: F; Race: WHITE							
Renal and urinary disorders/ Urinary incontinence/ INCONTINENCE DUE TO WORSENING RECTOCELE	2020-08-21 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Urinary incontinence/ URINARY INCONTINENCE DUE TO WORSENING CYSTOCELE	2020-08-21 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482032; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-09 08:00 (28)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ DIFFUSE MYALGIA	2020-09-10 08:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-10 08:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482033; Age (years): 75; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ TICK BITE TO LEG	2020-08-13 10:00 (1)/ 2020-08-15 10:00 (3)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482048; Age (years): 65; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-27 (47)/ 2020-11-06 (57)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-27 (47)/ 2020-11-06 (57)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Colitis/ ACUTE COLITIS	2020-10-27 (47)/ 2020-11-19 (70)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482048; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Campylobacter gastroenteritis/ CAMPYLOBACTER ENTERITIS	2020-11-04 (55)/ 2020-11-19 (70)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3482064; Age (years): 71; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash macular/ NON-URTICARIAL MACULAR RASH WITH BLANCHING ERYTHEMA ON LEFT DELTOID	2020-08-25 (9)/ 2020-09-04 (19)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482070; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Catheter site infection/ HICKMAN LINE SITE INFECTION	2020-09-24 (11)/ 2020-10-01 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482080; Age (years): 70; Sex: M; Race: WHITE							
Nervous system disorders/ Sciatica/ LEFT SIDED SCIATICA FLARE-UP	2020-10-07 (22)/ 2020-10-15 (30)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482089; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Onychomycosis/ FUNGAL TOENAIL	2020-11-01 (47)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3482113; Age (years): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ INTERMITTENT RHINORRHEA	2020-08-25 (5)/ 2020-09-21 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482118; Age (years): 68; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ HYPERTENSIVE EPISODE	2020-10-12 (22)/ 2020-10-12 (22)	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482134; Age (years): 70; Sex: M; Race: WHITE							
Psychiatric disorders/ Drug use disorder/ OPIOID USE DISORDER	2020-09-14 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482136; Age (years): 70; Sex: F; Race: WHITE							
Surgical and medical procedures/ Curetting of chalazion/ EXCISION OF CHALAZION RIGHT EYELID	2020-09-09 (16)/ 2020-09-09 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3482140; Age (years): 67; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-14 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482151; Age (years): 68; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF EXISTING KNEE PAIN	2020-09-01 (6)/ 2020-11-13 (79)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482155; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-08 (13)/ 2020-09-18 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-10-14 (20)/ 2020-10-19 (25)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482162; Age (years): 44; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDER PAIN	2020-10-04 (10)/ 2020-10-27 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482162; Age (years): 44; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ LEFT NECK PAIN	2020-10-04 (10)/ 2020-10-27 (33)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2020-10-09 (15)/ 2020-10-23 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482170; Age (years): 52; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Hepatobiliary disorders/ Cholelithiasis/ GALLSTONES	2020-09-23 (24)/ 2020-09-25 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: PARTICIPANT FOR FOLLOW UP WITH GENERAL SURGEON

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482170; Age (years): 52; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Surgical and medical procedures/ Cholecystectomy/ CHOLECYSTECTOMY	2020-10-19 (22)/ 2020-10-19 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482191; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Reproductive system and breast disorders/ Uterine polyp/ ENDOMETRIAL POLYP	2020-09-25 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482209; Age (years): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-01 (3)/ 2020-10-02 (4)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ CONGESTION, NASAL	2020-10-01 (3)/ 2020-10-09 (11)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482220; Age (years): 50; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-29 (31)/ 2020-11-03 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482227; Age (years): 34; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Hordeolum/ HORDEOLUM	2020-10-06 (5)/ 2020-10-12 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482242; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-25 (24)/ 2020-11-02 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-25 (24)/ 2020-11-02 (32)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482242; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-25 (24)/ 2020-11-06 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-10-25 (24)/ 2020-11-06 (36)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3482252; Age (years): 65; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-21 (8)/ 2020-11-05 (23)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3482254; Age (years): 61; Sex: M; Race: WHITE							
Nervous system disorders/ Post herpetic neuralgia/ NEUROPATHIC PAIN/POST HERPETIC NEURALGIA LEFT CHEST	2020-09-16 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482278; Age (years): 52; Sex: F; Race: MULTIPLE:					(b) (6)		
Musculoskeletal and connective tissue disorders/ Arthritis/ LEFT THUMB CARPO-METACARPAL ARTHRITIS , REQUIRING LOCAL JOINT STEROID INJECTION	2020-10-07 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3482283; Age (years): 46; Sex: M; Race: MULTIPLE:				(b) (6)			
Musculoskeletal and connective tissue disorders/ Neck pain/ LEFT SIDED NECK PAIN	2020-10-18 (10)/ 2020-10-21 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ LEFT SIDED HEADACHE	2020-10-18 (10)/ 2020-10-21 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482284; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-28 (13)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-05/ 2020-11-07)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-28 (13)/ 2020-10-31 (16)	Yes/ Yes/ No	4	Yes/2/3 (2020-10-29/ 2020-10-31)/4	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SHORTNESS OF BREATH & IMPAIRED CARDIAC FUNCTION (CHF)
Cardiac disorders/ Acute left ventricular failure/ ACUTE ON CHRONIC SYSTOLIC HEART FAILURE	2020-11-05 (21)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-05/ 2020-11-07)/4	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3482284; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chest pain/ CHEST PAIN	2020-11-16 (32)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-18/)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3482327; Age (years): 62; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-27 (5)/ 2020-11-02 (11)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	2020-10-27 (5)/ 2020-11-02 (11)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-27 (5)/ 2020-11-02 (11)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492009; Age (years): 55; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ KNEE PAIN	2020-11-09 (49)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3492023; Age (years): 52; Sex: M; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX	2020-11-04 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
General disorders and administration site conditions/ Early satiety/ EARLY SATIETY	2020-11-04 (41)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-11-04 (41)/ 2020-11-06 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492024; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Anxiety/ CHEST TIGHTNESS DUE TO ANXIETY	2020-09-08 (12)/ 2020-09-25 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492029; Age (years): 75; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Hand fracture/ BROKEN THUMB	2020-10-04 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3492040; Age (years): 64; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Fall/ FALL	2020-10-03 (5)/ 2020-10-03 (5)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Ligament sprain/ SPRAINED LOWER EXTREMITY	2020-10-03 (5)/ 2020-10-03 (5)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492040; Age (years): 64; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Toothache/ RIGHT BACK MOLAR TOOTH PAIN	2020-11-06 (39)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3492057; Age (years): 68; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-26 (24)/ 2020-10-15 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492058; Age (years): 69; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Haemorrhoids/ HEMORRHOIDS	2020-10-28 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492066; Age (years): 40; Sex: M; Race: WHITE							
Infections and infestations/ Skin infection/ RIGHT INDEX FINGER SKIN INFECTION	2020-11-09 (41)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3492069; Age (years): 85; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Rib fracture/ RIB FRACTURE X 2, LEFT MIDDLE	2020-10-31 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Wrist fracture/ LEFT WRIST FRACTURE	2020-10-31 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3492070; Age (years): 31; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA EXACERBATION	2020-09-16 (13)/ 2020-09-16 (13)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492078; Age (years): 93; Sex: M; Race: WHITE							
Vascular disorders/ Haematoma/ HEMATOMA OF THE R LEG	2020-11-03 (33)/ 2020-11-11 (41)	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3492095; Age (years): 38; Sex: M; Race: WHITE							
Investigations/ Oxygen saturation decreased/ LOW O2 SATURATION	2020-09-08 16:56 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-28 (21)/ 2020-10-20 (43)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Proctitis chlamydial/ CHLAMYDIA PROSTATITIS	2020-10-16 (11)/ 2020-10-23 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492121; Age (years): 78; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-22 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ TYPE II DIABETES	2020-10-22 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFICIENCY	2020-10-22 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3492123; Age (years): 53; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Hypoxia/ HYPOXIA	2020-10-09 (29)/ 2020-10-12 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492153; Age (years): 72; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Spinal compression fracture/ L2 VERTEBRAL COMPRESSION FRACTURE	2020-09-20 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ PAIN TO LEFT ILIUM	2020-09-20 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3492155; Age (years): 84; Sex: M; Race: WHITE							
Vascular disorders/ Peripheral artery occlusion/ PERIPHERAL VASCULAR DISEASE WITH ACUTE BLOCKAGE	2020-09-28 (14)/ 2020-10-23 (39)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492191; Age (years): 22; Sex: F; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Migraine/ HEADACHES RELATED TO MIGRAINE	2020-09-24 (8)/ 2020-10-02 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492193; Age (years): 69; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-26 (8)/ 2020-10-31 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492210; Age (years): 34; Sex: M; Race: WHITE							
Investigations/ Transaminases increased/ TRANSAMINITIS (MILDLY ELEVATED ALT) POSSIBLY WORSENING FATTY LIVER DISEASE	2020-10-30 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3492212; Age (years): 43; Sex: F; Race: OTHER: (b) (6)							
Reproductive system and breast disorders/ Ovarian cyst/ OVARIAN CYST	2020-11-15 (31)/ 2020-11-18 (34)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492214; Age (years): 28; Sex: M; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT-ANKLE JOINT PAIN	2020-10-26 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3492237; Age (years): 60; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-09-22 14:00 (1)/ 2020-10-09 (18)	No/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492243; Age (years): 50; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19 INFECTION	2020-11-07 (18)/ Ongoing	Yes/ Yes/ No	1	Yes/6	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3492262; Age (years): 36; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Constipation/ CONSTIPATION	2020-10-04 (10)/ 2020-10-07 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492262; Age (years): 36; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2020-10-04 (10)/ 2020-10-07 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3492271; Age (years): 74; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Blood and lymphatic system disorders/ Lymphadenopathy/ SUBMANDIBULAR LYMPHADENOPATHY	2020-10-29 14:50 (31)/ 2020-11-10 (43)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Swelling/ ENLARGED NECK R SIDE	2020-10-29 14:50 (31)/ 2020-11-10 (43)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492273; Age (years): 65; Sex: M; Race: OTHER: (b) (6)							
Injury, poisoning and procedural complications/ Road traffic accident/ CAR ACCIDENT	2020-10-06 (7)/ 2020-10-06 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Post-traumatic pain/ SHOULDER PAIN FROM CAR ACCIDENT	2020-10-06 (7)/ 2020-10-07 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3492292; Age (years): 27; Sex: F; Race: ASIAN							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT (STREPTOCOCCAL PHARYNGITIS)	2020-10-27 (22)/ 2020-11-06 (32)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3492308; Age (years): 43; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-30 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3502013; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-06 (47)/ 2020-11-08 (49)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502026; Age (years): 76; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT (IPSILATERAL) SUBMANDIBULAR LYMPHADENOPATHY	2020-09-09 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502026; Age (years): 76; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-21 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-21 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-10-21 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502026; Age (years): 76; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-21 (29)/ 2020-10-23 (31)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-21 (29)/ 2020-10-26 (34)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-21 (29)/ 2020-10-26 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3502028; Age (years): 60; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-22 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502028; Age (years): 60; Sex: M; Race: WHITE							
Endocrine disorders/ Hyperparathyroidism/ HYPERPARATHYROIDISM	2020-11-15 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Renal neoplasm/ KIDNEY TUMOR	2020-11-15 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Chronic kidney disease/ CHRONIC KIDNEY DISEASE	2020-11-15 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Osteopenia/ OSTEOPENIA	2020-11-18 (57)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3502029; Age (years): 69; Sex: M; Race: WHITE							
Endocrine disorders/ Thyroiditis/ THYROIDITIS	2020-11-12 (51)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3502037; Age (years): 60; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-24 12:00 (28)/ 2020-09-29 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502054; Age (years): 36; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Pelvic pain/ PELVIC PAIN	2020-09-07 (11)/ 2020-09-18 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3502058; Age (years): 44; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-26 06:00 (1)/ 2020-09-29 (5)	Yes/ Yes/ No	4	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3502058; Age (years): 44; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY ADENOPATHY - IPSILATERAL	2020-09-28 (4)/ Ongoing	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3502077; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-06 (8)/ 2020-10-16 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-28 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3502102; Age (years): 33; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA OF ENTIRE BODY	2020-09-08 (5)/ 2020-09-24 (21)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-11 (8)/ 2020-09-14 (11)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPITATORY INFECTION	2020-09-14 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3502104; Age (years): 43; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-09-19 (16)/ 2020-09-26 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-18 (17)/ 2020-10-24 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-18 (17)/ 2020-10-24 (23)	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	2020-10-18 (17)/ 2020-10-24 (23)	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502104; Age (years): 43; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	2020-10-18 (17)/ 2020-10-24 (23)	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-18 (17)/ 2020-10-24 (23)	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502127; Age (years): 38; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Breast neoplasm/ ATYPICAL VASCULAR LESION OF LEFT BREAST	2020-10-09 08:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502135; Age (years): 46; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-09-20 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3502161; Age (years): 58; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod sting/ BEE STING	2020-09-20 (7)/ 2020-09-20 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502163; Age (years): 50; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-25 (11)/ 2020-09-28 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3502170; Age (years): 49; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ Tooth infection/ INFECTED TOOTH	2020-10-01 (14)/ 2020-10-07 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502187; Age (years): 42; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Upper respiratory tract infection/ URI (COUGH CONGESTION, RHINORRHEA)	2020-11-08 (7)/ 2020-11-17 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502193; Age (years): 48; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-10-17 (12)/ 2020-10-25 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-21 (16)/ 2020-10-25 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3502209; Age (years): 49; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-31 (16)/ 2020-11-05 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Upper respiratory tract infection/ URI (CHILLS, FATIGUE, MYALGIA, H/A, RHINORRHEA, PHARYNGITIS)	2020-10-31 (16)/ 2020-11-11 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3502212; Age (years): 59; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chest discomfort/ CHEST PRESSURE	2020-10-24 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512005; Age (years): 54; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ FRACTURED ORAL MOLAR	2020-08-13 (9)/ 2020-08-13 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3512006; Age (years): 78; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA ON SCALP	2020-09-16 (15)/ 2020-09-29 (28)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3512008; Age (years): 57; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH LEFT DELTOID, NON-URTICARIAL; MACULOPAPULAR	2020-08-13 (9)/ 2020-08-18 (14)	Yes/ Yes/ No	1	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512015; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Hordeolum/ STYE LEFT EYE	2020-10-14 (41)/ 2020-10-26 (53)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512042; Age (years): 78; Sex: M; Race: WHITE							
Cardiac disorders/ Cardio-respiratory arrest/ CARDIOPULMONARY ARREST	2020-09-01 (21)/ 2020-09-01 (21)	Yes/ Yes/ No	4	Yes/1	NR/ NR	DOSE NOT CHANGED/ NONE	FATAL
Subject ID: US3512053; Age (years): 22; Sex: F; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT DISORDER	2020-09-12 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Psychiatric disorders/ Depression/ WORSENING DEPERSSION	2020-09-28 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512060; Age (years): 60; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF LOWER BACK PAIN	2020-08-28 (16)/ 2020-09-11 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512076; Age (years): 47; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ UPPER MIDDLE MUSCULOSKELETAL BACK PAIN	2020-09-24 (7)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3512078; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Wound infection/ PALM BRANCH THORN PUNCTURE OF LEFT FOREARM CAUSING INFECTION	2020-10-21 (41)/ 2020-11-02 (53)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512085; Age (years): 64; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING LEFT MEDIAL KNEE PAIN	2020-08-24 (10)/ 2020-08-28 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512111; Age (years): 38; Sex: M; Race: WHITE							
Endocrine disorders/ Thyroid mass/ 5 CM RIGHT THYROID MASS	2020-11-05 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512149; Age (years): 73; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-09-07 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Inguinal hernia/ LEFT SIDE INGUINAL HERNIA	2020-10-01 (9)/ 2020-11-19 (58)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512159; Age (years): 53; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 09:30 (1)/ 2020-09-03 19:00 (9)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Investigations/ Blood potassium decreased/ LOW POTASSIUM	2020-08-30 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Investigations/ Electrocardiogram T wave inversion/ INVERTED T-WAVES ON EKG	2020-08-30 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Blood and lymphatic system disorders/ Anaemia/ WORSENED ANEMIA	2020-09-08 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512159; Age (years): 53; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-08 (40)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Cellulitis/ CELLULITIS LOWER BACK	2020-11-19 (51)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512174; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ INTERMITTENT COUGH	2020-08-31 (5)/ 2020-09-13 (18)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3512175; Age (years): 64; Sex: M; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-09-17 (20)/ 2020-09-30 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512177; Age (years): 63; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis/ ATYPICAL DERMATITIS: LEFT POSTERIOR SCALP ITCHINESS	2020-10-03 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512193; Age (years): 77; Sex: F; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-10-27 (26)/ Ongoing	Yes/ Yes/ Yes	3	Yes/3 (2020-10-27/ 2020-10-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512231; Age (years): 42; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-11 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512231; Age (years): 42; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-16 (12)/ 2020-10-12 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3512233; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABCESS OF #7 TOOTH	2020-10-23 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512236; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTED AREA AROUND FOREIGN OBJECT IN RIGHT FOOT	2020-10-06 (32)/ 2020-10-13 (39)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3512261; Age (years): 59; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-30 (19)/ 2020-10-04 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512261; Age (years): 59; Sex: F; Race: ASIAN							
Gastrointestinal disorders/ Diverticulum/ DIVERTICULOSIS	2020-10-17 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3512262; Age (years): 78; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-27 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN
Subject ID: US3512264; Age (years): 45; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-14 (3)/ 2020-09-20 (9)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512287; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Abscess/ HIDRADENITIS SUPPURITIVA ABSCESS EXACERBATION (RIGHT ARM: 10 ABSCESSES) (LEFT AXILLARY REGION: 1 ABSCESS) (ABDOMEN: 1 ABSCESS)	2020-10-18 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3512288; Age (years): 47; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ BILATERAL SUBMANDIBULAR LYMPHADENOPATHY	2020-10-08 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-08 (8)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3512288; Age (years): 47; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-08 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522002; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Renal and urinary disorders/ Nephrolithiasis/ FLANK PAIN-PASSING KIDNEY STONE	2020-10-07 (36)/ 2020-10-07 (36)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522038; Age (years): 49; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash erythematous/ DIFFUSE ERYTHEMATOUS RASH (RIGHT SIDE OF BODY)	2020-08-18 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522038; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES/PAIN IN THEIR LEGS AND AROUND THEIR RIB CAGE AREA FOR 48 HOURS.	2020-08-18 (13)/ 2020-08-20 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522107; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Ear infection/ BILATERAL EAR INFECTION	2020-11-01 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522109; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ PAIN IN UPPER RIGHT CHEST NOS	2020-09-14 (5)/ 2020-09-15 (6)	Yes/ Yes/ No	4	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522137; Age (years): 63; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Nasal injury/ INJURED NOSE	2020-09-26 (17)/ 2020-10-09 (30)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3522140; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Exostosis/ WORSENING BONE SPUR PAIN BILATERAL HEELS	2020-09-25 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3522141; Age (years): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ KNEE PAIN	2020-09-22 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522142; Age (years): 55; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Post procedural haemorrhage/ NASAL BLEED FROM NP SWAB	2020-09-14 08:30 (28)/ 2020-09-21 (36)	Yes/ Yes/ No	2	No	NA/ R	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522173; Age (years): 42; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ RIGHT LOWER STOMACH PAIN	2020-10-27 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522181; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Groin pain/ NEUROLOGICAL GROIN PAIN	2020-10-12 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522186; Age (years): 68; Sex: M; Race: WHITE							
Investigations/ Blood urine present/ BLOOD IN URINE	2020-11-08 (52)/ 2020-11-08 (52)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522253; Age (years): 62; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ MID-BACK PAIN	2020-11-03 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522256; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Acute sinusitis/ ACUTE MAXILLARY SINUSITIS	2020-09-07 (19)/ 2020-09-23 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522284; Age (years): 69; Sex: F; Race: WHITE							
Nervous system disorders/ Sciatica/ SCIATICA	2020-09-23 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522286; Age (years): 66; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-21 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522312; Age (years): 34; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-31 (8)/ 2020-09-02 (10)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-31 (8)/ 2020-09-08 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-31 (8)/ 2020-09-08 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522349; Age (years): 54; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Constipation/ CONSTIPATION	2020-10-19 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522349; Age (years): 54; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-19 (27)/ 2020-11-02 (41)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-19 (27)/ 2020-11-02 (41)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-11-01 (40)/ 2020-11-02 (41)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522360; Age (years): 45; Sex: M; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS FLARE-UP	2020-10-26 (34)/ 2020-11-04 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522362; Age (years): 27; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ SHOULDER STRAIN (WHIPLASH)	2020-10-07 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Post-traumatic neck syndrome/ NECK STRAIN (WHIPLASH)	2020-10-07 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522368; Age (years): 48; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-11-11 (45)/ 2020-11-12 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3522373; Age (years): 71; Sex: M; Race: WHITE							
Investigations/ Prostatic specific antigen increased/ ELEVATED PSA	2020-10-30 (38)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522399; Age (years): 30; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ INCREASE IN ANXIETY	2020-10-06 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522401; Age (years): 66; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ RIGHT THUMB ARTHRITIS	2020-09-11 (16)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522418; Age (years): 75; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chest pain/ SUBSTERNAL CHEST PAIN	2020-10-06 20:00 (2)/ 2020-10-07 05:31 (2)	Yes/ Yes/ No	4	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Angina pectoris/ CARDIAC CHEST PAIN	2020-11-11 (38)/ 2020-11-11 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522491; Age (years): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ WORSENING GERD	2020-09-15 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	2020-09-15 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Joint stiffness/ WORSENING JOINT STIFFNESS	2020-09-15 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522491; Age (years): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-15 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZE	2020-09-15 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522529; Age (years): 44; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Intervertebral disc degeneration/ DEGENERATIVE DISC DISEASE (MULTILEVEL)	2020-09-21 (20)/ 2020-09-23 (22)	Yes/ Yes/ No	4	Yes/3 (2020-09-21/ 2020-09-23)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522556; Age (years): 49; Sex: M; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-11 (44)/ 2020-11-14 (47)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-11 (44)/ 2020-11-14 (47)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNING NOSE	2020-11-11 (44)/ 2020-11-14 (47)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522562; Age (years): 57; Sex: M; Race: MULTIPLE: (b) (6)							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ NEW DIAGNOSIS OF TYPE 2 DIABETES	2020-10-29 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3522569; Age (years): 60; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ TRANSVERSE FRACTURE (NONDISPLACED) AT THE DISTAL PHALANX OF RIGHT 5TH TOE	2020-11-07 (33)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3522609; Age (years): 46; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis/ EAR DERMATITIS (LEFT)	2020-09-14 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3522613; Age (years): 54; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ THROAT ITCHING	2020-09-09 (2)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3522664; Age (years): 62; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RIGHT DELTOID MACULAR, NON-URTICARIAL REDNESS AT INJECTION SITE 120MM BY 86MM OBLONG	2020-09-23 (13)/ 2020-09-25 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3522665; Age (years): 76; Sex: F; Race: WHITE							
Nervous system disorders/ Lumbar radiculopathy/ LUMBAR RADICULOPATHY	2020-10-23 (43)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3522687; Age (years): 72; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ NEW DX OF LYMPHADENOPATHY, RIGHT AXILLARY DURING ROUTINE MAMMOGRAM.	2020-09-24 (10)/ 2020-09-24 (10)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532002; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING BACK PAIN	2020-09-08 (1)/ 2020-10-14 (37)	Yes/ Yes/ No	4	Yes/3 (2020-09-16/ 2020-09-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3532011; Age (years): 48; Sex: M; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS, (COUGH, CONGESTION, RUNNY NOSE, SORE THROAT	2020-10-15 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Subject ID: US3532042; Age (years): 74; Sex: F; Race: ASIAN							
Surgical and medical procedures/ Hip arthroplasty/ RIGHT HIP REPLACEMENT	2020-10-19 (36)/ 2020-10-19 (36)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532045; Age (years): 56; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ RIGHT HAND LACERATION	2020-10-07 (24)/ 2020-10-07 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532059; Age (years): 71; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Actinic keratosis/ WORSENING OF FACIAL ACTINIC KERATOSIS	2020-10-05 (20)/ 2020-10-11 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3532062; Age (years): 67; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Neurodermatitis/ PRURIGO NODULARIS FLARE UP	2020-08-28 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Subject ID: US3532067; Age (years): 77; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-28 (44)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3532083; Age (years): 50; Sex: F; Race: WHITE							
Cardiac disorders/ Palpitations/ HEART PALPITATIONS	2020-10-05 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3532093; Age (years): 71; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteopenia/ OSTEOPENIA	2020-09-29 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3532094; Age (years): 76; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONE	2020-10-19 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Subject ID: US3532108; Age (years): 66; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ OPTICAL HEADACHE	2020-09-24 (2)/ 2020-09-24 (2)	Yes/ Yes/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3532113; Age (years): 68; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle rupture/ TORN BACK MUSCLE (LOWER RIGHT)	2020-08-26 (6)/ 2020-10-05 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3532122; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-28 (8)/ 2020-10-23 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532127; Age (years): 68; Sex: M; Race: WHITE							
Investigations/ Prostatic specific antigen increased/ ELEVATED PSA	2020-11-05 (45)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532135; Age (years): 45; Sex: M; Race: WHITE							
Infections and infestations/ Conjunctivitis/ DRY EYES/ CONJUNCTIVITIS	2020-10-03 (12)/ 2020-10-30 (39)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532143; Age (years): 72; Sex: M; Race: WHITE							
Renal and urinary disorders/ Urinary hesitation/ INCREASING URINARY HESITANCY	2020-09-23 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Paraesthesia/ INCREASED L SHOULDER PARESTHESIA	2020-10-05 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3532149; Age (years): 66; Sex: M; Race: WHITE							
Cardiac disorders/ Cardiomyopathy/ CATECHOLAMINE CARDIOMYOPATHY	2020-10-19 (27)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532152; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Head injury/ HEAD INJURY	2020-10-03 (10)/ 2020-10-15 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Skin laceration/ FOREHEAD LACERATION	2020-10-03 (10)/ 2020-10-15 (22)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Infections and infestations/ Impetigo/ IMPETIGO RIGHT SIDE ABD AND ARM	2020-10-09 (16)/ 2020-10-15 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532182; Age (years): 56; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-10-05 (8)/ 2020-10-12 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532192; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Renal cancer/ KIDNEY CANCER	2020-10-09 (4)/ Ongoing	Yes/ Yes/ No	3	Yes/2/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3532224; Age (years): 77; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-02 (3)/ 2020-10-10 (11)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532225; Age (years): 69; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ STRESS RELATED SKIN RASH ON SHOULDERS, BACK AND GENITAL AREA	2020-10-19 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532230; Age (years): 72; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Limb injury/ RIGHT ARM INJURY	2020-09-26 (24)/ 2020-10-06 (34)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3532231; Age (years): 76; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Pneumonia/ COMMUNITY ACQUIRED PNEUMONIA	2020-10-10 (10)/ 2020-10-16 (16)	Yes/ Yes/ No	4	Yes/3 (2020-10-10/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Toxic encephalopathy/ TOXIC ENCEPHALOPATHY	2020-10-10 (10)/ 2020-10-16 (16)	Yes/ Yes/ No	4	Yes/3 (2020-10-10/ 2020-10-16)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Hepatobiliary disorders/ Hepatic steatosis/ HEPATIC STEATOSIS	2020-10-14 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532252; Age (years): 70; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ WORSENING CRACKED RIGHT MOLAR	2020-10-12 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-12 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3532259; Age (years): 32; Sex: M; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-23 (17)/ 2020-11-11 (36)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532261; Age (years): 66; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma/ SQUAMOUS CELL CARCINOMA	2020-09-29 (21)/ 2020-10-21 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3532277; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-04 (25)/ 2020-10-06 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-16 (9)/ 2020-10-26 (19)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532278; Age (years): 31; Sex: M; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ RHINOVIRUS	2020-10-18 (11)/ 2020-10-24 (17)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3532279; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-05 (26)/ 2020-10-21 (42)	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3532281; Age (years): 69; Sex: M; Race: WHITE							
Surgical and medical procedures/ Ankle arthroplasty/ LEFT ANKLE REPLACEMENT	2020-10-23 (18)/ 2020-10-25 (20)	Yes/ Yes/ No	4	Yes/3 (2020-10-23/ 2020-10-25)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3542018; Age (years): 66; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2020-09-09 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542029; Age (years): 61; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-02 (14)/ 2020-09-12 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542046; Age (years): 46; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT HIP PAIN	2020-10-01 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542058; Age (years): 26; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-10-09 (18)/ 2020-10-24 (33)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542071; Age (years): 69; Sex: M; Race: MULTIPLE: (b) (6)							
Eye disorders/ Eye pain/ EYE PAIN POST-CATARACT SURGERY	2020-09-28 (4)/ 2020-10-01 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Pruritus/ GENERALIZED PRURITUS	2020-10-13 (19)/ 2020-11-10 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542087; Age (years): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Alopecia/ HAIR LOSS	2020-09-28 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542105; Age (years): 80; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-27 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542108; Age (years): 46; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling face/ CHEEK SWELLING, BILATERAL	2020-09-30 10:00 (1)/ 2020-10-05 (7)	Yes/ Yes/ No	2	Yes/6	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3542142; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Renal and urinary disorders/ Urinary hesitation/ WORSENED URINARY HESITANCY	2020-10-19 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542158; Age (years): 39; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Anal fissure/ ANAL FISSURE	2020-09-25 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542198; Age (years): 62; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ TOOTH FRACTURE	2020-09-22 (13)/ 2020-10-30 (51)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3542206; Age (years): 71; Sex: M; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-10 17:02 (1)/ 2020-09-22 (13)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-22 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542239; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Renal and urinary disorders/ Dysuria/ BURNING DYSURIA	2020-09-20 (6)/ 2020-10-11 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Cerebral small vessel ischaemic disease/ CEREBRAL SMALL VESSEL ISCHEMIC DISEASE	2020-11-03 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542241; Age (years): 64; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Plasma cell myeloma/ WORSENING MULTIPLE MYELOMA	2020-10-20 (7)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542285; Age (years): 74; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	2020-10-20 18:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3542299; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Gingivitis/ GINGIVITIS	2020-09-30 (6)/ 2020-10-13 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Depression/ DEPRESSION	2020-10-20 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3542309; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Congenital, familial and genetic disorders/ Arnold-Chiari malformation/ CHIARI MALFORMATION	2020-11-13 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542309; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Skin laceration/ POSTERIOR SCALP LACERATION	2020-11-13 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Subarachnoid haemorrhage/ SUBARACHNOID HEMORRHAGE	2020-11-13 (17)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-13/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Syncope/ SYNCOPE	2020-11-13 (17)/ 2020-11-13 (17)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3542312; Age (years): 46; Sex: M; Race: MULTIPLE: (b) (6)							
Musculoskeletal and connective tissue disorders/ Muscle tightness/ SHOULDERS/NECK MUSCLE TENSION	2020-10-26 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3542332; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Seizure/ EXACERBATION OF SEIZURE DISORDER	2020-11-07 (30)/ 2020-11-08 (31)	Yes/ Yes/ No	3	Yes/3 (2020-11-07/ 2020-11-08)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552022; Age (years): 66; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATED RIGHT FOOT	2020-09-18 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Psychiatric disorders/ Anxiety/ ANXIETY	2020-09-21 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552022; Age (years): 66; Sex: M; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTED RIGHT FOOT	2020-09-30 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3552024; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN, NON-SPECIFIED	2020-08-24 (12)/ 2020-09-11 (30)	Yes/ Yes/ No	3	Yes/3 (2020-08-29/ 2020-08-30)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552035; Age (years): 55; Sex: M; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-09-04 (22)/ 2020-09-21 (39)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552050; Age (years): 55; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-03 (16)/ 2020-10-09 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552053; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTH ACHE	2020-08-28 (12)/ 2020-09-04 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-15 12:00 (1)/ 2020-09-21 (8)	Yes/ Yes/ Yes	4	Yes/3 (2020-09-17/ 2020-09-18)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Vomiting/ INTRACTABLE VOMITING	2020-09-15 12:00 (1)/ 2020-09-21 (8)	Yes/ Yes/ Yes	4	Yes/3 (2020-09-17/ 2020-09-18)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Cardiac disorders/ Arrhythmia/ WORSENING ARRHYTHMIA	2020-11-10 (58)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552053; Age (years): 65; Sex: F; Race: WHITE							
Cardiac disorders/ Mitral valve incompetence/ NITRILE VALVE REGURGITATION	2020-11-19 (67)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Migraine/ MIGRAINES	2020-11-19 (67)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3552063; Age (years): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Reproductive system and breast disorders/ Dysfunctional uterine bleeding/ DYSFUNCTIONAL UTERINE BLEEDING	2020-09-02 (16)/ 2020-09-22 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552100; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Ear infection/ BILATERAL EAR INFECTION	2020-10-28 (41)/ 2020-11-06 (50)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552101; Age (years): 66; Sex: M; Race: WHITE							
Nervous system disorders/ Cervical radiculopathy/ CERVICAL RADICULOPATHY	2020-10-21 (36)/ 2020-11-06 (52)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552105; Age (years): 65; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-11 (25)/ 2020-10-17 (31)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-11 (25)/ 2020-10-18 (32)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-11 (25)/ 2020-10-26 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552119; Age (years): 43; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-09-08 (19)/ 2020-09-09 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-08 (19)/ 2020-09-10 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-08 (19)/ 2020-09-10 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552130; Age (years): 65; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-09-28 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552144; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-08-30 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3552145; Age (years): 46; Sex: M; Race: ASIAN							
Infections and infestations/ Tooth infection/ WISDOM TOOTH INFECTION	2020-10-10 (20)/ 2020-10-10 (20)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3552178; Age (years): 49; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D. DEFICIENCY	2020-11-02 (42)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552189; Age (years): 21; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-27 15:04 (1)/ 2020-09-15 (21)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-27 15:04 (1)/ 2020-09-17 (23)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS (NON-CARDIAC, RELATED TO ANXIETY)	2020-09-03 (9)/ 2020-09-07 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552189; Age (years): 21; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-09-03 (9)/ 2020-09-07 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-05 (11)/ 2020-09-15 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ GENERALIZED BODY ACHES	2020-09-07 (13)/ 2020-09-07 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-07 (13)/ 2020-09-07 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552189; Age (years): 21; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Constipation/ CONSTIPATION	2020-09-22 (28)/ 2020-10-07 (43)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-25 (31)/ 2020-10-02 (38)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-25 (31)/ 2020-10-07 (43)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-25 (31)/ 2020-10-07 (43)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552189; Age (years): 21; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-07 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION	2020-10-07 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-07 (43)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-16 (52)/ 2020-10-28 (64)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552189; Age (years): 21; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Meniscus injury/ LEFT KNEE MENISCUS TEAR	2020-10-27 (63)/ 2020-11-05 (72)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Spinal column injury/ L5 BACK INJURY	2020-11-05 (72)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3552191; Age (years): 66; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH ON EXERTION	2020-09-30 (8)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-09/ 2020-10-10)	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552191; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS	2020-10-09 (17)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2020-10-09 (17)/ 2020-10-20 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA	2020-10-09 (17)/ 2020-11-09 (48)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Endocrine disorders/ Hyperthyroidism/ HYPERTHYROIDISM	2020-10-26 (34)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552247; Age (years): 68; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-01 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3552251; Age (years): 65; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-26 (27)/ 2020-10-01 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-27 (28)/ 2020-09-28 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-27 (28)/ 2020-09-30 (31)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552251; Age (years): 65; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-27 (28)/ 2020-09-30 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-27 (28)/ 2020-10-12 (43)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3552313; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-21 (24)/ 2020-11-05 (39)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552320; Age (years): 29; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-07 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552352; Age (years): 67; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-02 08:38 (25)/ 2020-10-23 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552356; Age (years): 44; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Skin papilloma/ WARTS	2020-10-08 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3552364; Age (years): 67; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ WORSENED NECK MUSCLE SPASM	2020-09-19 (12)/ 2020-09-20 (13)	Yes/ Yes/ No	2	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552371; Age (years): 56; Sex: F; Race: WHITE							
Investigations/ Hepatic enzyme increased/ ELEVATED LIVER ENZYMES	2020-09-16 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552371; Age (years): 56; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ankle fracture/ FRACTURED LEFT ANKLE	2020-09-16 (9)/ 2020-11-19 (73)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Renal cell carcinoma/ RIGHT KIDNEY RENAL CELL CARCINOMA	2020-10-08 (31)/ 2020-11-13 (67)	Yes/ Yes/ No	4	Yes/3 (2020-11-12/ 2020-11-13)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Psychiatric disorders/ Anxiety/ ANXIETY	2020-10-22 (45)/ 2020-10-29 (52)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552410; Age (years): 67; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING BACK PAIN	2020-11-21 (44)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3552434; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-10-12 (28)/ 2020-10-12 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3552464; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-10-20 (5)/ 2020-10-27 (12)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-11-22 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3552488; Age (years): 22; Sex: M; Race: ASIAN							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-09-30 (8)/ 2020-11-04 (43)	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3552499; Age (years): 73; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT FOOT PAIN	2020-10-21 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3552524; Age (years): 45; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-20 (12)/ 2020-10-23 (15)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3562058; Age (years): 69; Sex: M; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-09-03 (15)/ 2020-09-10 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562077; Age (years): 60; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ HIP PAIN BILATERAL	2020-10-07 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ KNEE PAIN BILATERAL	2020-10-07 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3562081; Age (years): 51; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Injection site rash/ RASH INJECTION SITE	2020-09-03 (9)/ 2020-09-03 (9)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562082; Age (years): 54; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Joint dislocation/ DISLOCATE LEFT SHOULDER PAIN	2020-09-16 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3562083; Age (years): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Neck pain/ RIGHT SIDE NECK PAIN	2020-09-02 (8)/ 2020-09-05 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3562092; Age (years): 57; Sex: F; Race: WHITE							
Investigations/ Hormone level abnormal/ LOW HORMONE	2020-10-20 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3562118; Age (years): 56; Sex: F; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Proctalgia/ PAIN RECTAL AREA	2020-09-10 (7)/ 2020-09-12 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562118; Age (years): 56; Sex: F; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN BILATERAL LEGS	2020-09-10 (7)/ 2020-09-12 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Vulvovaginal pain/ PAIN VULVA GENITAL AREA	2020-09-10 (7)/ 2020-09-12 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Haematochezia/ BLOOD IN STOOL	2020-09-11 (8)/ 2020-09-12 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-11 (8)/ 2020-09-12 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562143; Age (years): 74; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoporosis/ OSTEOPOROSIS	2020-10-13 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3562145; Age (years): 51; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-01 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3562157; Age (years): 62; Sex: F; Race: MULTIPLE:				(b) (6)			
Infections and infestations/ Herpes zoster/ SHINGLES	2020-09-17 (7)/ 2020-10-07 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Colorectal cancer/ COLORECTAL CANCER	2020-11-04 (22)/ Ongoing	Yes/ Yes/ No	4	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562157; Age (years): 62; Sex: F; Race: MULTIPLE: (b) (6)							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Pelvic neoplasm/ PELVIC CANCER	2020-11-04 (22)/ Ongoing	Yes/ Yes/ No	4	Yes/6	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3562170; Age (years): 61; Sex: F; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-10-14 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3562178; Age (years): 33; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF CHRONIC BACK PAIN	2020-10-15 (29)/ 2020-10-22 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3562183; Age (years): 44; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-29 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3562188; Age (years): 36; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH PATCHY UPPER BODY NON URTICARIAL	2020-10-10 (20)/ 2020-10-13 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3562190; Age (years): 63; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-05 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3562224; Age (years): 53; Sex: M; Race: ASIAN							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-12 08:23 (1)/ Ongoing	No/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3562230; Age (years): 45; Sex: M; Race: OTHER: (b) (6)							
Hepatobiliary disorders/ Hepatic mass/ LIVER NODULE	2020-11-07 (24)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-07/ 2020-11-17)	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572057; Age (years): 51; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-24 (3)/ 2020-09-29 (8)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572077; Age (years): 30; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sneezing/ SNEEZING	2020-09-04 00:00 (11)/ 2020-09-05 00:00 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3572080; Age (years): 48; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-11-14 (53)/ 2020-11-18 (57)	Yes/ Yes/ Yes	1	No		/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572109; Age (years): 62; Sex: M; Race: WHITE							
Nervous system disorders/ Seizure/ SEIZURES	2020-08-28 (2)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572154; Age (years): 64; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT HEEL PAIN	2020-09-21 08:00 (21)/ 2020-09-23 15:00 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT SPRAINED ANKLE	2020-09-22 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3572162; Age (years): 50; Sex: M; Race: NOT REPORTED							
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES (BILATERAL HIPS AND BILATERAL KNEES)	2020-09-29 14:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No		/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572166; Age (years): 72; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-08 (7)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3572178; Age (years): 38; Sex: F; Race: WHITE							
Renal and urinary disorders/ Dysuria/ DYSURIA	2020-09-20 (18)/ 2020-09-23 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572208; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-10-25 (20)/ Ongoing	Yes/ Yes/ No	1	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572208; Age (years): 59; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-25 (20)/ Ongoing	Yes/ Yes/ No	1	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-25 (20)/ Ongoing	Yes/ Yes/ No	1	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3572270; Age (years): 64; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-22 (14)/ Ongoing	Yes/ Yes/ No	1	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572270; Age (years): 64; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ SEVERE ITCHING	2020-10-22 (14)/ 2020-10-24 (16)	Yes/ Yes/ No	3	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ RASH	2020-10-22 (14)/ 2020-10-24 (16)	Yes/ Yes/ No	3	No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572322; Age (years): 28; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-10-21 (2)/ 2020-10-25 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3572326; Age (years): 36; Sex: F; Race: WHITE							
Nervous system disorders/ Carpal tunnel syndrome/ RIGHT CARPAL TUNNEL PAIN	2020-10-19 (22)/ Ongoing	Yes/ Yes/ No	2	No		/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3572347; Age (years): 45; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-03 (9)/ Ongoing	Yes/ Yes/ Yes	2	No	NA/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3582002; Age (years): 69; Sex: M; Race: WHITE							
Cardiac disorders/ Angina pectoris/ EXERTIONAL ANGINA	2020-09-03 (17)/ 2020-09-03 (17)	Yes/ Yes/ No	2	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582027; Age (years): 73; Sex: M; Race: WHITE							
Vascular disorders/ Systolic hypertension/ SYSTOLIC HYPERTENSION	2020-08-21 16:40 (1)/ 2020-08-28 14:15 (7)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582049; Age (years): 48; Sex: M; Race: ASIAN							
Metabolism and nutrition disorders/ Gout/ GOUT EXACERBATION	2020-09-13 (19)/ 2020-09-17 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3582054; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-11-01 (41)/ 2020-11-22 (62)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3582075; Age (years): 67; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal stiffness/ FINGER STIFFNESS	2020-09-07 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Pain in extremity/ FINGER PAIN	2020-09-07 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3582099; Age (years): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Helicobacter infection/ H. PYLORI	2020-10-27 (22)/ 2020-11-11 (37)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582114; Age (years): 40; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site lymphadenopathy/ LEFT (INJECTION SIDE) AXILLARY LYMPHADENOPATHY	2020-09-08 18:00 (1)/ 2020-10-06 23:59 (29)	Yes/ Yes/ Yes	3	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (LEFT DELTOID), ERYTHEMA ONLY WITHOUT URTICARIA OR RASH.	2020-09-15 (8)/ 2020-09-20 (13)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582114; Age (years): 40; Sex: M; Race: ASIAN							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE	2020-09-15 (8)/ 2020-09-20 (13)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3582127; Age (years): 30; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY AXILLARY (LEFT SIDE) INJECTION SIDE	2020-09-16 (8)/ 2020-09-21 (13)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash maculo-papular/ LEFT UPPER ARM RASH, MACULOPAPULAR, NON-URTICARIAL	2020-09-17 (9)/ 2020-09-25 (17)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582131; Age (years): 28; Sex: F; Race: MULTIPLE:					(b) (6)		
Injury, poisoning and procedural complications/ Clavicle fracture/ LEFT CLAVICLE FRACTURE	2020-09-17 (8)/ 2020-09-29 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Toothache/ WISDOM TOOTH PAIN	2020-09-20 (11)/ 2020-10-09 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3582134; Age (years): 36; Sex: M; Race: MULTIPLE:					(b) (6)		
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT AXILLARY LYMPHADENOPATHY	2020-09-15 (6)/ 2020-09-17 (8)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3582140; Age (years): 75; Sex: F; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Swelling/ NON-URTICARIAL SWELLING LEFT AXILLA	2020-11-06 (30)/	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	
Subject ID: US3582153; Age (years): 51; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Otitis media/ MIDDLE EAR INFECTION	2020-10-20 (7)/ 2020-10-27 (14)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3592022; Age (years): 35; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Bone fragmentation/ BONE FRAGMENT RIGHT ANKLE	2020-08-19 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592032; Age (years): 37; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION LEFT FOREARM	2020-08-11 (6)/ 2020-09-04 (30)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3592043; Age (years): 50; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-07 (4)/ 2020-09-25 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-13 (10)/ 2020-09-25 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-13 (10)/ 2020-09-25 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592052; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-15 (41)/ Ongoing	Yes/ Yes/ No		No		DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592111; Age (years): 73; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diverticular perforation/ PERFORATED DIVERTICULITIS	2020-11-03 (58)/ Ongoing	Yes/ Yes/ Yes	2	Yes/3 (2020-11-05/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Colonic abscess/ COLON ABSCESS	2020-11-05 (60)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592154; Age (years): 59; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Stomatitis/ SORES IN MOUTH	2020-11-04 (56)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592154; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-11-04 (56)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Tongue disorder/ THICK TONGUE	2020-11-11 (63)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592163; Age (years): 37; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-25 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-25 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592163; Age (years): 37; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-25 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592180; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-20 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3592232; Age (years): 79; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP PAIN	2020-08-25 (6)/ Ongoing	Yes/ Yes/ No	4	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592232; Age (years): 79; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST WALL PAIN, MUSCULOSKELETAL, SECONDARY TO FALL	2020-08-25 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Benign neoplasm of thyroid gland/ THYROID NODULE, RIGHT, BENIGN	2020-08-25 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592232; Age (years): 79; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Femoral neck fracture/ RIGHT SUBCAPITAL FEMORAL NECK FRACTURE, DISPLACED GARDEN III	2020-08-25 (6)/ 2020-10-05 (47)	Yes/ Yes/ No	3	Yes/3 (2020-08-25/ 2020-08-28)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	2020-08-27 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Blood and lymphatic system disorders/ Leukocytosis/ AFEBRILE LEUKOCYTOSIS	2020-08-27 (8)/ 2020-08-28 (9)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3592247; Age (years): 87; Sex: F; Race: WHITE							
Cardiac disorders/ Bradycardia/ BRADYCARDIA	2020-11-10 (46)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-10/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3592247; Age (years): 87; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-11-10 (46)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-11-10 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3602017; Age (years): 45; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-10-14 (15)/ 2020-10-17 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3602027; Age (years): 61; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament injury/ LIGAMENT TEAR (LEFT KNEE)	2020-09-28 (19)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602033; Age (years): 39; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Arthropod sting/ BEE STING	2020-09-13 (3)/ 2020-09-14 (4)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Arthralgia/ ELBOW PAIN	2020-10-28 (13)/ 2020-10-31 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602040; Age (years): 30; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ INCREASING DEPRESSION (DUE TO HOLIDAY SEASON AND INCREASING COVID-19 INFECTION RESURGENCE)	2020-11-02 (14)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602045; Age (years): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Reproductive system and breast disorders/ Menstrual disorder/ ABNORMAL MENSTRUATION (LASTING >7 DAYS AND HEAVY VS NORMALLY 5 DAYS)	2020-10-01 (16)/ 2020-10-12 (27)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3602067; Age (years): 43; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Nerve compression/ PINCHED NERVE	2020-10-12 (22)/ 2020-11-18 (59)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602070; Age (years): 56; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rosacea/ ROSACEA	2020-11-17 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602090; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Gingivitis/ GUM PAIN (R/T "INFECTED POCKET" BETWEEN 2ND AND 3RD BACK TEETH ON LEFT SIDE).	2020-11-05 (16)/ 2020-11-05 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3602098; Age (years): 33; Sex: M; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Throat irritation/ "SCRATCHY-ITCHY" THROAT	2020-10-15 (8)/ 2020-10-17 (10)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3602134; Age (years): 36; Sex: F; Race: UNKNOWN							
General disorders and administration site conditions/ Injection site induration/ INDURATION (HARDNESS) AT INJECTION SITE	2020-11-04 18:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3602134; Age (years): 36; Sex: F; Race: UNKNOWN							
General disorders and administration site conditions/ Injection site swelling/ SWELLING AT INJECTION SITE (LEFT DELTOID)	2020-11-04 18:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3612004; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ RETICULATE MACULAR ERYTHEMA AT INJECTION SITE, RIGHT ARM	2020-09-07 (8)/ 2020-09-11 (12)	Yes/ Yes/ No	3	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3612006; Age (years): 60; Sex: F; Race: ASIAN							
Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	2020-10-27 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3612013; Age (years): 64; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Oedema peripheral/ RIGHT LEG EDEMA	2020-09-05 (3)/ 2020-09-07 (5)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622004; Age (years): 77; Sex: M; Race: ASIAN							
Injury, poisoning and procedural complications/ Fibula fracture/ LEFT FIBULA FRACTURE	2020-08-24 (15)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3622015; Age (years): 72; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-20 (9)/ 2020-08-26 (15)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-20 (9)/ 2020-08-27 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622015; Age (years): 72; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER	2020-08-20 (9)/ 2020-08-27 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-21 (10)/ 2020-08-25 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622028; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-08-14 20:00 (1)/ 2020-08-21 (8)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-15 (2)/ 2020-08-21 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622028; Age (years): 38; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ STUFFY NOSE	2020-08-19 (6)/ 2020-08-21 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622029; Age (years): 68; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Onychomycosis/ FUNGUS - TOENAILS (RIGHT FOOT)	2020-08-28 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3622051; Age (years): 57; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATS	2020-09-16 08:00 (1)/ 2020-09-18 (4)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622057; Age (years): 38; Sex: F; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Anaemia/ ANEMIA	2020-09-29 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622057; Age (years): 38; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-09-29 (9)/ 2020-10-09 (19)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-11-06 (47)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622059; Age (years): 43; Sex: M; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-15 (28)/ 2020-10-15 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-15 (28)/ 2020-10-19 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622059; Age (years): 43; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-16 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-16 (29)/ 2020-10-16 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Hyperhidrosis/ DIAPHORETIC	2020-10-16 (29)/ 2020-10-16 (29)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-17 (30)/ 2020-10-18 (31)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622059; Age (years): 43; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-17 (30)/ 2020-10-18 (31)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622072; Age (years): 36; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-22 (32)/ 2020-10-26 (36)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-22 (32)/ 2020-10-26 (36)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622072; Age (years): 36; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-22 (32)/ 2020-11-05 (46)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-22 (32)/ 2020-11-05 (46)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORT OF BREATH	2020-10-23 (33)/ 2020-10-23 (33)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622072; Age (years): 36; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-23 (33)/ 2020-10-25 (35)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3622074; Age (years): 59; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INDURATION AT INJECTION SITE	2020-09-22 12:05 (1)/ 2020-09-25 (4)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622075; Age (years): 73; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ HIP INFLAMMATION	2020-09-30 (9)/ 2020-10-06 (15)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622080; Age (years): 51; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site induration/ INDURATION AT INJECTION SITE	2020-09-23 08:10 (1)/ 2020-09-24 (2)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622120; Age (years): 59; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ MUSCULAR CHEST PAIN	2020-09-01 02:00 (1)/ 2020-09-01 02:02 (1)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3622126; Age (years): 55; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-27 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622126; Age (years): 55; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Ear discomfort/ BILATERAL EAR FULLNESS	2020-10-28 (30)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-31 (33)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622134; Age (years): 81; Sex: M; Race: WHITE							
Renal and urinary disorders/ Chronic kidney disease/ KIDNEY DISEASE STAGE 3 (BILATERAL)	2020-10-21 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622192; Age (years): 69; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Diabetes mellitus inadequate control/ UNCONTROLLED DIABETES	2020-09-18 (3)/ 2020-11-06 (52)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3622217; Age (years): 65; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Latent tuberculosis/ LATENT TB	2020-09-28 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3622236; Age (years): 53; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Post procedural swelling/ SWELLING FROM WISDOM TOOTH REMOVAL (TOP TWO)	2020-11-16 (22)/ 2020-11-23 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Procedural pain/ PAIN FROM WISDOM TOOTH REMOVAL (TOP TWO)	2020-11-16 (22)/ 2020-11-23 (29)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632012; Age (years): 59; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION DIAGNOSIS	2020-10-01 (11)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632058; Age (years): 37; Sex: F; Race: NOT REPORTED							
Nervous system disorders/ Thoracic outlet syndrome/ PECTORALIS MINOR OF ULNAR NERVE	2020-09-28 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Cardiac disorders/ Sinus tachycardia/ INAPPROPRIATE SINUS TACHYCARDIA	2020-10-23 (18)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3632070; Age (years): 83; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin lesion/ LESION ON LEFT WRIST	2020-09-23 (14)/ 2020-10-28 (49)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2020-10-25 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632070; Age (years): 83; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL CARCINOMA ON LEFT WRIST	2020-10-28 (21)/ 2020-10-28 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3632100; Age (years): 69; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ HIP PAIN (RIGHT)	2020-10-14 (23)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN (WORSENING)	2020-10-14 (23)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3632100; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Staphylococcal infection/ STAPHYLOCOCCUS INFECTION	2020-10-27 (8)/ 2020-11-01 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632101; Age (years): 24; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	2020-10-22 (3)/ 2020-10-23 (4)	Yes/ Yes/ No	3	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632115; Age (years): 20; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ EAR INFECTION (RIGHT)	2020-10-19 (14)/ 2020-11-02 (28)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3632124; Age (years): 31; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Joint injury/ KNEE INJURY	2020-11-16 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642016; Age (years): 70; Sex: M; Race: ASIAN							
Infections and infestations/ Herpes simplex/ HSV-1 INFECTION, ORAL	2020-09-16 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3642020; Age (years): 66; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-05 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3642190; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ Herpes simplex/ HERPES SIMPLEX INFECTION	2020-10-08 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3642214; Age (years): 72; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Skin lesion/ SKIN LESION	2020-10-12 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642217; Age (years): 72; Sex: F; Race: WHITE							
Nervous system disorders/ Piriformis syndrome/ PIRIFORMIS SYNDROME	2020-10-06 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3642220; Age (years): 44; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-16 (7)/ 2020-10-20 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3642250; Age (years): 65; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE	2020-11-18 (33)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3642275; Age (years): 32; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-13 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3642284; Age (years): 20; Sex: M; Race: OTHER: (b) (6)							
Injury, poisoning and procedural complications/ Procedural dizziness/ LIGHTHEADEDNESS POST BLOOD DRAW	2020-09-28 16:20 (1)/ 2020-09-28 16:37 (1)	No/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3642292; Age (years): 50; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ Herpes zoster/ SUBJECT WITH EXACERBATION OF SHINGLES	2020-10-11 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3642312; Age (years): 46; Sex: F; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-11-16 (7)/ 2020-11-16 (7)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3652010; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Abdominal discomfort/ LEFT UPPER QUADRANT DISCOMFORT	2020-09-15 (6)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3652024; Age (years): 26; Sex: M; Race: MULTIPLE:					(b) (6)		
Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	2020-09-20 (6)/ 2020-09-28 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652038; Age (years): 34; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID-19	2020-10-25 (31)/ 2020-11-06 (43)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3652047; Age (years): 24; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ UNDERARM GLAND SWELLING OR TENDERNESS (EDIARY)	2020-10-09 (8)/ 2020-10-10 (9)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662003; Age (years): 69; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rosacea/ ROSACEA, UNSPECIFIED	2020-09-29 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662005; Age (years): 70; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Middle ear effusion/ CLEAR FLUID BEHIND BILATERAL TYMPANIC MEMBRANES	2020-10-05 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662028; Age (years): 35; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Vertigo positional/ BENIGN PAROXYSMAL VERTIGO	2020-09-24 (15)/ 2020-09-28 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662036; Age (years): 61; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ POSTERIOR TIBIAL TENDINITIS, RIGHT LEG	2020-09-10 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662036; Age (years): 61; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ OTHER SPECIFIED ARTHRITIS, MULTIPLE SITES (BOTH KNEES)	2020-10-27 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662038; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-22 (16)/ 2020-10-31 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Paranasal sinus discomfort/ SINUS PRESSURE	2020-10-22 (16)/ 2020-10-31 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662038; Age (years): 66; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-10-22 (16)/ 2020-10-31 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Upper-airway cough syndrome/ POST NASAL DRIP	2020-10-22 (16)/ 2020-10-31 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662040; Age (years): 63; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA, UNSPECIFIED	2020-10-01 (30)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662040; Age (years): 63; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Nail infection/ NAIL INFECTION IN RIGHT MIDDLE FINGER	2020-10-30 (25)/ 2020-11-10 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662046; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASM LEFT SIDE OF TRAPEZIUS	2020-10-10 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS LEFT SIDE OF NECK	2020-10-10 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662046; Age (years): 59; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle tightness/ TIGHTNESS OF RIGHT TRAPEZIUS	2020-10-10 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ TENDERNESS BILATERALLY ON PALPATION OVER TRAPEZIUS	2020-10-10 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662050; Age (years): 54; Sex: M; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-02 21:30 (1)/ 2020-10-03 14:50 (2)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662050; Age (years): 54; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-03 12:00 (2)/ 2020-10-03 14:50 (2)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-16 (15)/ 2020-10-22 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Eye disorders/ Eye pruritus/ ITCHY EYES	2020-10-19 (18)/ 2020-10-21 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-19 (18)/ 2020-10-21 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662050; Age (years): 54; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-19 (18)/ 2020-10-21 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662075; Age (years): 71; Sex: M; Race: MULTIPLE: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-10-02 (23)/ 2020-10-30 (51)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 (28)/ 2020-10-30 (51)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662075; Age (years): 71; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Pain/ GENERALIZED BODY ACHES, IN AM	2020-10-07 (28)/ 2020-10-30 (51)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-07 (28)/ 2020-10-30 (51)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Faeces soft/ SOFT STOOL, 2 EPISODES	2020-10-08 (29)/ 2020-10-09 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662077; Age (years): 65; Sex: M; Race: WHITE							
Infections and infestations/ Chronic sinusitis/ CHRONIC MAXILLARY SINUSITIS	2020-09-16 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Nasopharyngeal neoplasm benign/ BENIGN NEO NASAL CAV MID EAR & SINUS	2020-09-16 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662085; Age (years): 70; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Upper-airway cough syndrome/ POST NASAL DRIP	2020-10-13 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662085; Age (years): 70; Sex: M; Race: WHITE							
Nervous system disorders/ Sinus headache/ SINUS HEADACHE	2020-10-13 (6)/ 2020-10-16 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-13 (6)/ 2020-10-28 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662091; Age (years): 49; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-02 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Dizziness/ DIZZINESS	2020-10-02 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662091; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-02 (19)/ 2020-10-06 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Muscular weakness/ WEAK LEGS	2020-10-02 (19)/ 2020-10-07 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-02 (19)/ 2020-10-07 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662091; Age (years): 49; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	2020-10-02 (19)/ 2020-10-09 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sinus pain/ SINUS PAIN	2020-10-02 (19)/ 2020-10-28 (45)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ CHEST CONGESTION	2020-10-03 (20)/ 2020-10-09 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662091; Age (years): 49; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-10-03 (20)/ 2020-10-28 (45)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sneezing/ SNEEZING	2020-10-04 (21)/ 2020-10-08 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Asthenia/ DISSEMINATED BODY WEAKNESS	2020-11-22 (42)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662091; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ BODY TEMPERATURE (POTENTIAL FEVER-100.1)	2020-11-23 (43)/ Ongoing	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662100; Age (years): 50; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Non-cardiac chest pain/ SHOOTING PAIN THROUGH BACK TO CHEST, NON CARDIAC	2020-09-16 08:47 (1)/ 2020-09-16 08:57 (1)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Flushing/ FLUSHING, FACE/NECK	2020-09-16 08:47 (1)/ 2020-09-16 08:57 (1)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662107; Age (years): 42; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Headache/ HEADACHE	2020-09-21 (6)/ 2020-09-24 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-25 (10)/ 2020-10-06 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Eye disorders/ Vision blurred/ BLURRED VISION WHEN SEEING OBJECTS FAR AWAY	2020-10-02 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Gastric ulcer/ ACUTE GASTRIC ULCER WITHOUT HEMORRAGE/PERFORATION/OBSTRUCTION	2020-10-07 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662107; Age (years): 42; Sex: M; Race: OTHER: (b) (6)							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTRO-ESOPHAGEAL REFLUX DISEASE	2020-10-07 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Oesophageal ulcer/ ULCER OF ESOPHAGUS	2020-10-07 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Otitis externa/ DIFFUSE OTITIS EXTERNA, BILATERAL	2020-10-27 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662107; Age (years): 42; Sex: M; Race: OTHER: (b) (6)							
Musculoskeletal and connective tissue disorders/ Muscle tightness/ TIGHT MUSCLE IN RIGHT ARM	2020-11-10 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662109; Age (years): 64; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Joint swelling/ SWELLING, LATERAL MALLELOUS BILATERAL ANKLES	2020-10-15 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ CHEST CONGESTION	2020-10-19 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662112; Age (years): 78; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Nail disorder/ OTHER SPECIFIED DISEASE OF NAIL	2020-10-06 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ CHEST CONGESTION	2020-11-04 (17)/ 2020-11-06 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Laryngitis/ ACUTE LARYNGITIS W/O METION OF OBSTRUCTION	2020-11-04 (17)/ 2020-11-08 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662112; Age (years): 78; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Dysphonia/ THROAT HOARSENESS	2020-11-04 (17)/ 2020-11-08 (21)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Upper-airway cough syndrome/ POST NASAL DRIP	2020-11-05 (18)/ 2020-11-10 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662121; Age (years): 39; Sex: F; Race: OTHER: (b) (6)							
Injury, poisoning and procedural complications/ Skin laceration/ LASCERATED LEFT THUMB	2020-10-08 (18)/ 2020-10-08 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Limb injury/ PAIN IN CUT FINGER	2020-10-08 (18)/ 2020-10-11 (21)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662122; Age (years): 47; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-05 (15)/ 2020-10-06 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3662134; Age (years): 59; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Periodontal disease/ WORSENING PERIODONTAL DISEASE	2020-11-20 (26)/ 2020-11-20 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3662135; Age (years): 48; Sex: M; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Feeling hot/ SENSATION OF HEAT IN RIGHT LEG	2020-10-08 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662135; Age (years): 48; Sex: M; Race: OTHER: (b) (6)							
Nervous system disorders/ Sciatica/ SCIATICA PAIN IN RIGHT LEG	2020-10-08 (15)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3662137; Age (years): 39; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-10-06 (12)/ 2020-10-13 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-10-06 (12)/ 2020-10-13 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3662146; Age (years): 61; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Ear and labyrinth disorders/ Ear canal erythema/ BILATERAL ERYTHEMA PRESENT IN EXTERNAL CANAL	2020-10-27 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3662149; Age (years): 57; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Hyperaesthesia teeth/ TOOTH SENSITIVITY TO HOT/COLD	2020-10-03 (3)/ 2020-10-14 (14)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Toothache/ TOOTH ACHE, MOVES AROUND IN MOUTH, NOT ONE SPECIFIC AREA	2020-10-03 (3)/ 2020-10-14 (14)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Reproductive system and breast disorders/ Breast pain/ BILATERAL BREAST PAIN AROUND NIPPLE AREA	2020-10-08 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672010; Age (years): 20; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	2020-08-06 (1)/ 2020-08-06 (1)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672035; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection/ RESPIRATORY TRACT INFECTION	2020-11-17 (71)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3672036; Age (years): 69; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2020-09-10 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672051; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-09-24 (17)/ 2020-10-02 (25)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672069; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS (SINUS INFECTION)	2020-10-03 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3672092; Age (years): 52; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site erythema/ REDNESS AT INJECTION SITE (L)	2020-08-21 (9)/ 2020-08-27 (15)	Yes/ Yes/ No	3	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672105; Age (years): 29; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS DUE TO POISON IVY (MEDIAL LEFT CALF)	2020-08-24 (12)/ 2020-09-08 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672115; Age (years): 30; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Head injury/ HEAD WOUND	2020-10-02 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3672118; Age (years): 59; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ TYPE II DIABETES	2020-08-20 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672122; Age (years): 31; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ HERNIATED DISC	2020-08-14 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-10-16 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN
Subject ID: US3672125; Age (years): 74; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Respiratory disorder/ RESPIRATORY TRACT ILLNESS	2020-10-05 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3672158; Age (years): 62; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-08 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672163; Age (years): 56; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ RIGHT ARM ERYTHEMA (URTICARIAL)	2020-08-26 (9)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Induration/ RIGHT ARM INDURATION	2020-08-26 (9)/ 2020-09-02 (16)	Yes/ Yes/ No	2	No	R/ NR	DRUG WITHDRAWN/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672176; Age (years): 22; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection/ RESPIRATORY TRACT INFECTION	2020-10-15 (31)/ 2020-10-27 (43)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672209; Age (years): 40; Sex: F; Race: WHITE							
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-09-28 (12)/ 2020-10-05 (19)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672226; Age (years): 72; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ RIGHT FOOT LACERATION	2020-10-26 (39)/ 2020-11-02 (46)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3672237; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Rotator cuff syndrome/ LEFT TORN ROTATOR CUFF	2020-09-06 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3672246; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-16 (27)/ 2020-09-22 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672261; Age (years): 27; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Swelling face/ RIGHT LOWER FACE SWELLING.	2020-09-08 (19)/ 2020-09-16 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3672264; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-11-11 (49)/ 2020-11-16 (54)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672303; Age (years): 24; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-06 (13)/ 2020-10-19 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3672309; Age (years): 56; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Meniscus injury/ TORN R KNEE MENISCUS	2020-09-24 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672315; Age (years): 64; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ DM TYPE II	2020-09-03 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3672316; Age (years): 60; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ FRACTURED RIGHT IV TOE	2020-08-26 (1)/ 2020-10-31 (67)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Respiratory tract infection/ RESPIRATORY TRACT INFECTION	2020-10-06 (14)/ 2020-10-10 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672325; Age (years): 47; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ INTERMITTENT L UPPER ARM PAIN	2020-08-27 12:30 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Memory impairment/ FORGETFULNESS	2020-09-30 (3)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Muscle twitching/ INTERMITTENT HEAD TWITCHING	2020-10-09 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672351; Age (years): 77; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ TENDONITIS OF RIGHT ANKLE	2020-09-10 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3672377; Age (years): 31; Sex: F; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-09-09 (13)/ 2020-10-17 (51)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Pruritus/ GENERALIZED PRURITIS	2020-09-11 (15)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Urticaria/ WORSENING OF URITICARIA	2020-09-21 (25)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3672388; Age (years): 70; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chest discomfort/ SUBSTERNAL PRESSURE	2020-09-08 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3672398; Age (years): 76; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ PULLED BACK MUSCLE	2020-09-24 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3682017; Age (years): 41; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Colitis/ COLITIS	2020-09-21 (27)/ 2020-10-13 (49)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	2020-09-21 (27)/ 2020-10-13 (49)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682026; Age (years): 34; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ L CALF MUSCLE PAIN	2020-09-25 12:15 (1)/ Ongoing	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3682029; Age (years): 35; Sex: M; Race: ASIAN							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-04 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3682053; Age (years): 44; Sex: M; Race: MULTIPLE: (b) (6)							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION FOREHEAD	2020-09-09 (7)/ 2020-09-09 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3682125; Age (years): 55; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Food poisoning/ FOOD POISONING	2020-11-02 (20)/ 2020-11-04 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682127; Age (years): 38; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFICIENCY	2020-09-20 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL HIP PAIN	2020-10-23 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3682128; Age (years): 37; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Melanocytic naevus/ HIGH RISK MOLE - STOMACH , LEFT NARES	2020-10-12 (27)/ 2020-10-12 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682128; Age (years): 37; Sex: M; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT HYPERACTIVE DISORDER	2020-10-23 (10)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3682134; Age (years): 46; Sex: M; Race: OTHER: (b) (6)							
Infections and infestations/ Cellulitis/ CELLULITIS OF LEFT FOOT	2020-09-21 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Infections and infestations/ Osteomyelitis/ OSTEOMYELITIS OF LEFT FOOT	2020-09-21 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Concussion/ CONCUSSION	2020-09-24 (8)/ 2020-10-04 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3682135; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-04 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3682156; Age (years): 38; Sex: M; Race: WHITE							
Nervous system disorders/ Presyncope/ VASOVAGAL REACTION	2020-09-22 15:07 (1)/ 2020-09-22 15:08 (1)	Yes/ Yes/ No	1	No	NR/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3692020; Age (years): 50; Sex: F; Race: WHITE							
Eye disorders/ Scleritis/ EYE REDNESS (SCLERITIS)	2020-09-04 (7)/ 2020-09-07 (10)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692083; Age (years): 51; Sex: M; Race: WHITE							
Infections and infestations/ Conjunctivitis/ PINK EYE BILATERAL	2020-09-28 (20)/ 2020-11-03 (56)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692086; Age (years): 37; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-09-12 (3)/ 2020-09-21 (12)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692121; Age (years): 21; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP THROAT	2020-10-20 (8)/ 2020-10-25 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3692157; Age (years): 49; Sex: F; Race: NOT REPORTED							
Reproductive system and breast disorders/ Menorrhagia/ VAGINAL BLEEDING (HEAVY BLEEDING DUE TO PERI-MENOPAUSE)	2020-10-25 (6)/ 2020-11-01 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3692197; Age (years): 42; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-22 (8)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692202; Age (years): 21; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Fungal infection/ YEAST INFECTION	2020-11-01 (11)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3692205; Age (years): 58; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Tachypnoea/ TACHYPNEA	2020-11-20 10:40 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMA- FACIAL AREA	2020-11-20 12:23 (1)/ 2020-11-20 13:30 (1)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702045; Age (years): 61; Sex: M; Race: WHITE							
Infections and infestations/ Ear infection/ EAR INFECTION	2020-09-26 (3)/ 2020-10-03 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Ear infection/ EAR PAIN (RELATED TO EAR INFECTION)	2020-09-26 (3)/ 2020-10-03 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Parainfluenzae virus infection/ UPPER RESPIRATORY INFECTION DUE TO PARAINFLUENZA	2020-10-08 (15)/ 2020-10-15 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3702045; Age (years): 61; Sex: M; Race: WHITE							
Nervous system disorders/ Hypoaesthesia/ LEFT FOOT NUMBNESS (ASSOCIATED WITH SLEEP POSITION)	2020-11-07 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3712037; Age (years): 34; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Non-cardiac chest pain/ CHEST PAIN (NON-CARDIAC)	2020-09-30 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3712108; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ BODY ACHES (LEG PAIN) (FROM PLAYING GOLF)	2020-09-24 (3)/ 2020-09-24 (3)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3712193; Age (years): 59; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Bone contusion/ FALL WITH BRUISED RIBS	2020-10-22 (8)/ 2020-10-25 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3712218; Age (years): 37; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ BROKEN LEFT FOOT	2020-10-16 (-7)/ 2020-10-23 (1)	No/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3712225; Age (years): 54; Sex: F; Race: WHITE							
Infections and infestations/ Otitis externa/ RIGHT EXTERNAL EAR INFECTION	2020-10-21 (3)/ 2020-11-11 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3712249; Age (years): 27; Sex: F; Race: WHITE							
Infections and infestations/ Gonorrhoea/ GONORRHEA	2020-11-18 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3712251; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Otitis externa/ RIGHT OUTER EAR INFECTION	2020-11-11 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3712310; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Onychomycosis/ ONYCHOMYCOSIS	2020-10-27 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3722022; Age (years): 64; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastric ulcer/ STOMACH ULCER	2020-10-16 (45)/ 2020-10-27 (56)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722119; Age (years): 59; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Constipation/ CONSTIPATION	2020-10-14 (42)/ 2020-10-19 (47)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722184; Age (years): 60; Sex: F; Race: WHITE							
Eye disorders/ Blepharitis/ BLEPHARITIS	2020-10-18 (40)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3722197; Age (years): 41; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEVER (ORAL)	2020-08-18 (8)/ 2020-08-19 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3722236; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-09-12 (31)/ 2020-09-13 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-09-12 (31)/ 2020-09-13 (32)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722236; Age (years): 68; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Chills/ CHILLS	2020-09-13 (32)/ 2020-09-13 (32)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-09-13 (32)/ 2020-09-15 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3722282; Age (years): 36; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-08-29 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-29 (15)/ 2020-09-16 (33)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3722282; Age (years): 36; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-04 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3722358; Age (years): 59; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-19 (27)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3722360; Age (years): 35; Sex: F; Race: ASIAN							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-23 (29)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732022; Age (years): 52; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-02 (29)/ 2020-10-03 (30)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732025; Age (years): 23; Sex: M; Race: WHITE							
Infections and infestations/ Viral pharyngitis/ VIRAL PHARYNGITIS	2020-10-03 (26)/ 2020-10-12 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732027; Age (years): 33; Sex: M; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Blister/ HAND AND FEET BLISTERS	2020-08-17 (11)/ 2020-08-24 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-06 (3)/ 2020-09-07 (4)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash/ GENERAL BODY RASH	2020-09-27 (24)/ 2020-10-03 (30)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732029; Age (years): 67; Sex: M; Race: WHITE							
Infections and infestations/ Localised infection/ INFECTION OF RIGHT SECOND TOE	2020-10-03 (27)/ 2020-10-10 (34)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732046; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-15 (69)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732069; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-14 (65)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732079; Age (years): 38; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-05 (22)/ 2020-10-09 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732099; Age (years): 64; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Pyrexia/ FEBRILE ILLNESS	2020-09-30 (15)/ 2020-10-01 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732100; Age (years): 76; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 (11)/ 2020-10-05 (13)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES (GENERAL)	2020-10-03 (11)/ 2020-10-05 (13)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732123; Age (years): 48; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-29 (39)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732123; Age (years): 48; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Adnexa uteri pain/ BILATERAL OVARY PAIN	2020-11-07 (48)/ 2020-11-14 (55)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732125; Age (years): 54; Sex: M; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS (SHORTNESS OF BREATH, CHILLS, BODY ACHES, FATIGUE, HEADACHE, COUGH, SORE THROAT)	2020-10-22 (35)/ 2020-10-25 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732127; Age (years): 42; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Pelvic pain/ PELVIC PAIN	2020-09-21 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732132; Age (years): 73; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Rectal cancer/ RECTAL CARCINOMA	2020-09-01 (12)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732150; Age (years): 26; Sex: F; Race: WHITE							
Infections and infestations/ Skin infection/ POSTERIOR NECK INFECTION	2020-11-06 (47)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LEFT SUPRACLAVICULAR LYMPH NODE INFLAMMATION	2020-11-07 (48)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732158; Age (years): 67; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Motion sickness/ SEA SICK	2020-09-26 (6)/ 2020-09-26 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732161; Age (years): 62; Sex: F; Race: WHITE							
Infections and infestations/ Rhinovirus infection/ HUMAN RHINOVIRUS	2020-09-21 (28)/ 2020-09-23 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732167; Age (years): 78; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-08-25 15:43 (1)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732168; Age (years): 67; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tenosynovitis stenosans/ RIGHT HAND STENOSING TENOSYNOVITIS	2020-10-22 (31)/ 2020-10-30 (39)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3732183; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ BACK PAIN, LEFT FLANK, MUSCULOSKELETAL	2020-09-16 (22)/ 2020-09-18 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732183; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE CRAMPS	2020-09-21 (27)/ 2020-10-21 (57)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732192; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-26 (32)/ 2020-10-31 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Head injury/ OCCIPITAL HEAD INJURY	2020-10-26 (32)/ 2020-10-31 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732202; Age (years): 59; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-11-07 (44)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732205; Age (years): 55; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT HIP FLEXOR STRAIN	2020-09-04 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Cough/ WORSENING INTERMITTENT COUGH	2020-10-01 (7)/ 2020-10-29 (35)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732250; Age (years): 42; Sex: M; Race: ASIAN							
Nervous system disorders/ Presyncope/ VASOGAL EVENT	2020-09-01 15:19 (1)/ 2020-09-01 16:00 (1)	No/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-01 16:06 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732260; Age (years): 18; Sex: F; Race: MULTIPLE: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-07 (6)/ 2020-10-05 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Gastroenteritis/ ACUTE GASTROENTERITIS	2020-09-08 (7)/ 2020-09-09 (8)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-19 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3732262; Age (years): 37; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMATIC COVID-19	2020-09-06 (5)/ 2020-09-19 (18)	Yes/ Yes/ No	1	No	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732279; Age (years): 53; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-02 20:01 (1)/ 2020-10-19 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-02 (32)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732282; Age (years): 73; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal stiffness/ LEFT ARM STIFFNESS	2020-09-29 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732283; Age (years): 72; Sex: F; Race: WHITE							
Nervous system disorders/ Dizziness/ DIZZINESS	2020-09-28 (25)/ 2020-09-28 (25)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732283; Age (years): 72; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthritis/ EXACERBATION OF ARTHRITIS	2020-11-05 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3732286; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Viral rhinitis/ RHINITIS, VIRAL	2020-09-16 (13)/ 2020-09-17 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 (1)/ 2020-10-24 (18)	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732286; Age (years): 29; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ GENERALIZED JOINT ACHES	2020-10-07 (1)/ 2020-10-24 (18)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Myalgia/ GENERALIZED MUSCLE ACHES	2020-10-07 (1)/ 2020-10-24 (18)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-07 (1)/ 2020-10-24 (18)	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Cyst/ LEFT NECK CYST	2020-10-13 (7)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732300; Age (years): 20; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-07 17:16 (1)/ 2020-10-16 18:00 (10)	Yes/ Yes/ Yes	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3732311; Age (years): 32; Sex: F; Race: WHITE							
Product issues/ Device dislocation/ DISPLACED LEFT BREAST SILICONE IMPLANT	2020-09-29 (20)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DRUG WITHDRAWN/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732322; Age (years): 69; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-31 (25)/ 2020-11-02 (27)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pyrexia/ FEVER (103 F)	2020-11-03 (28)/ 2020-11-03 (28)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732325; Age (years): 35; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-10-12 18:23 (1)/ 2020-10-26 (15)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732327; Age (years): 40; Sex: M; Race: MULTIPLE: (b) (6)							
Infections and infestations/ Laryngitis viral/ VIRAL LARYNGITIS	2020-10-25 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3732333; Age (years): 49; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT SITE OF INJECTION	2020-09-15 12:16 (1)/ 2020-09-15 16:00 (1)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-11-03 (22)/ 2020-11-09 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732342; Age (years): 32; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ LEFT AXILLARY PRURITIS	2020-09-16 (2)/ 2020-10-23 (39)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Enterovirus infection/ ENTEROVIRUS	2020-10-02 (18)/ 2020-10-06 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Rhinovirus infection/ HUMAN RHINOVIRUS	2020-10-02 (18)/ 2020-10-06 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3732351; Age (years): 57; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ CONTUSION GREAT TOE RIGHT	2020-09-27 (12)/ 2020-09-29 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3732356; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS	2020-11-15 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742001; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ TYPE II DIABETES	2020-11-10 (58)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742036; Age (years): 50; Sex: F; Race: ASIAN							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-11-01 (45)/ 2020-11-11 (55)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742048; Age (years): 71; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ SUPERFICIAL BASAL CELL CARCINOMA RIGHT SHOULDER	2020-10-26 (31)/ 2020-11-16 (52)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Squamous cell carcinoma of skin/ SUPERFICIAL SQUAMOUS CARCINOMA LEFT LEG	2020-10-26 (31)/ 2020-11-16 (52)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3742053; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-09 (52)/ Ongoing	Yes/ Yes/ Yes	2	No	NR/ NR	NOT APPLICABLE/ NONE	

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Subject ID: US3742053; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-10 (53)/ Ongoing	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	
Subject ID: US3742060; Age (years): 38; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE/ HAND	2020-09-30 (9)/ 2020-10-01 (10)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742103; Age (years): 32; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Arthropod bite/ TICK BITE	2020-10-25 (33)/ 2020-10-29 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742105; Age (years): 70; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ KNEE PAIN	2020-10-04 (12)/ 2020-11-04 (43)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742125; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-09-23 (21)/ 2020-10-29 (57)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3742132; Age (years): 28; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS UNSPECIFIED	2020-10-18 (24)/ 2020-10-25 (31)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742134; Age (years): 55; Sex: M; Race: WHITE							
Surgical and medical procedures/ Endodontic procedure/ ROOT CANAL	2020-09-28 (4)/ 2020-09-28 (4)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Renal and urinary disorders/ Nephrolithiasis/ RENAL CALCULUS	2020-10-01 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742137; Age (years): 40; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Ear pain/ OTALGIA	2020-09-22 (26)/ 2020-09-26 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742156; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Pharyngitis/ UPPER RESPIRATORY THROAT INFECTION	2020-09-10 (13)/ 2020-09-17 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742169; Age (years): 57; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Rheumatoid arthritis/ RHEUMATOID ARTHRITIS	2020-08-31 23:00 (1)/ Ongoing	Yes/ Yes/ No	2	Yes/6	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Infections and infestations/ Viral infection/ VIRAL ILLNESS UNSPECIFIED	2020-10-31 (62)/ 2020-11-14 (76)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742173; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS USPECIFIED	2020-09-22 (23)/ 2020-09-30 (31)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-22 (20)/ 2020-10-22 (20)	Yes/ Yes/ Yes	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742175; Age (years): 43; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Injury, poisoning and procedural complications/ Injury/ TRAUMATIC INJURY	2020-10-07 (10)/ 2020-10-15 (18)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Limb injury/ TRAUMATIC INJURY LEFT HAND	2020-10-07 (10)/ 2020-10-15 (18)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742176; Age (years): 73; Sex: F; Race: WHITE							
Surgical and medical procedures/ Skin cyst excision/ EXCISION OF MUCUS CYST RIGHT INDEX FINGER	2020-10-28 (31)/ 2020-11-20 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3742208; Age (years): 22; Sex: F; Race: WHITE							
Infections and infestations/ Oral herpes/ COLD SORE	2020-09-24 (23)/ 2020-09-25 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ UTI	2020-09-25 (24)/ 2020-09-30 (29)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-09-25 (24)/ 2020-10-16 (45)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742208; Age (years): 22; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-08 (35)/ 2020-11-14 (41)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ CONGESTION /NASAL	2020-11-09 (36)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3742220; Age (years): 65; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Viral infection/ VIRAL ILLNESS UNSPECIFIED	2020-10-02 (5)/ 2020-10-07 (10)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742223; Age (years): 29; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS	2020-09-29 (27)/ 2020-10-10 (38)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742224; Age (years): 57; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pruritus/ L DELTOID PRURITUS	2020-09-10 (8)/ 2020-09-13 (11)	Yes/ Yes/ No	2	No	R/ R	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742237; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Viral infection/ VIRAL ILLNESS UNSPECIFIED	2020-10-20 (16)/ 2020-11-01 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742337; Age (years): 46; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media/ OTITIS MEDIA	2020-10-30 (19)/ 2020-11-17 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742344; Age (years): 71; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTH #18 PAIN	2020-09-29 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742349; Age (years): 68; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Rectal haemorrhage/ RECTAL BLEEDING	2020-09-22 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3742357; Age (years): 53; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Skin laceration/ RIGHT MIDDLE FINER LACERATION	2020-10-13 (27)/ 2020-11-02 (47)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742375; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Pneumonia/ PNEUMONIA	2020-10-18 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Neck mass/ LUMP ON RIGHT NECK	2020-10-19 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742375; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Staphylococcal skin infection/ STAPH SKIN INFECTION ON NOSE	2020-10-22 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Mass/ LUMP CLAVICLE AREA LEFT SIDE	2020-10-23 (8)/ 2020-10-27 (12)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-10-24 (9)/ 2020-10-31 (16)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742393; Age (years): 31; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-10-18 (5)/ 2020-10-27 (14)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742417; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ Oral herpes/ ORAL HERPES SIMPLEX	2020-10-25 (11)/ 2020-11-04 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3742427; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-11-11 (26)/ 2020-11-13 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742431; Age (years): 20; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck mass/ LUMP ON LEFT SIDE OF NECK	2020-10-25 (9)/ 2020-11-14 (29)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3742438; Age (years): 53; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ DIFFUSE TRANSIENT RASH	2020-10-24 (8)/ 2020-11-08 (23)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3742469; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-10-23 (31)/ 2020-10-29 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752008; Age (years): 79; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-07 15:20 (1)/ 2020-08-14 (8)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752009; Age (years): 44; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-31 (25)/ 2020-09-10 (35)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752031; Age (years): 64; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-10-01 (21)/ 2020-10-03 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752034; Age (years): 60; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Chest discomfort/ CHEST PRESSURE	2020-10-20 (41)/ 2020-10-21 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-20 (41)/ 2020-10-21 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2020-10-20 (41)/ 2020-10-21 (42)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752034; Age (years): 60; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-20 (41)/ 2020-11-05 (57)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752056; Age (years): 44; Sex: F; Race: ASIAN							
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-11-04 (55)/ 2020-11-05 (56)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sneezing/ SNEEZING	2020-11-04 (55)/ 2020-11-05 (56)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-11-04 (55)/ 2020-11-07 (58)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3752056; Age (years): 44; Sex: F; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-06 (57)/ 2020-11-17 (68)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-11-09 (60)/ 2020-11-09 (60)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752082; Age (years): 34; Sex: F; Race: WHITE							
Ear and labyrinth disorders/ Ear pain/ EAR PAIN	2020-08-18 (6)/ 2020-08-28 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-08-18 (6)/ 2020-08-28 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3752082; Age (years): 34; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-08-18 (6)/ 2020-08-28 (16)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752084; Age (years): 32; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ BODY/JOINT ACHES	2020-10-19 (40)/ 2020-10-19 (40)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-10-19 (40)/ 2020-10-23 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Subject ID: US3752084; Age (years): 32; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-19 (40)/ 2020-10-25 (46)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-19 (40)/ 2020-10-25 (46)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-23 (44)/ 2020-10-23 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752087; Age (years): 44; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-30 (20)/ 2020-10-04 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752087; Age (years): 44; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ NASAL DRAINAGE	2020-09-30 (20)/ 2020-10-04 (24)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752094; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Cystitis/ BLADDER INFECTION	2020-09-29 (21)/ 2020-10-06 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-22 (44)/ 2020-10-23 (45)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752116; Age (years): 59; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Post-traumatic pain/ PAIN IN LEFT ARM DUE TO MVA	2020-10-01 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752116; Age (years): 59; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Post-traumatic pain/ PAIN IN LEFT SHOULDER DUE TO MVA	2020-10-01 (18)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752129; Age (years): 46; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Papillary thyroid cancer/ PAPILLARY THYROID CARCINOMA	2020-10-01 (11)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-10-02/ 2020-10-03)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	UNKNOWN
Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	2020-10-02 (12)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752129; Age (years): 46; Sex: F; Race: WHITE							
Surgical and medical procedures/ Thyroidectomy/ TOTAL THYROIDECTOMY	2020-10-02 (12)/ 2020-10-02 (12)	Yes/ Yes/ No	4	Yes/3 (2020-10-02/ 2020-10-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752133; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-10-25 (41)/ 2020-10-28 (44)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-25 (41)/ 2020-10-28 (44)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752152; Age (years): 61; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-21 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	UNKNOWN

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752153; Age (years): 71; Sex: F; Race: WHITE							
Surgical and medical procedures/ Knee arthroplasty/ TOTAL RIGHT KNEE ARTHROPLASTY REQUIRING HOSPITALIZATION	2020-11-10 (56)/ 2020-11-10 (56)	Yes/ Yes/ No	4	Yes/3 (2020-11-10/ 2020-11-11)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752173; Age (years): 77; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE							
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-11-01 (45)/ 2020-11-01 (45)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ NONE	FATAL
Subject ID: US3752176; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Skin infection/ SKIN INFECTION LEFT LOWER LEG	2020-09-30 (14)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3752178; Age (years): 69; Sex: F; Race: WHITE							
Renal and urinary disorders/ Pollakiuria/ URINARY FREQUENCY	2020-10-07 (22)/ 2020-10-09 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752188; Age (years): 37; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-30 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-30 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-30 (9)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752190; Age (years): 47; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-04 (11)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHE	2020-10-05 (12)/ 2020-10-07 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ NASAL DRAINAGE	2020-10-05 (12)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-10 (17)/ 2020-10-10 (17)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752195; Age (years): 20; Sex: F; Race: WHITE							
Nervous system disorders/ Tardive dyskinesia/ TARDIVE DYSKINESIA	2020-10-15 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3752206; Age (years): 72; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Hernia/ HERNIA	2020-11-18 (58)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3752227; Age (years): 45; Sex: F; Race: WHITE							
Nervous system disorders/ Carpal tunnel syndrome/ CARPAL TUNNEL SYNDROME ON THE RIGHT	2020-10-17 (23)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3752245; Age (years): 67; Sex: F; Race: WHITE							
Nervous system disorders/ Facial paralysis/ BELL'S PALSY	2020-11-06 (32)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2020-11-06/ 2020-11-07)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752248; Age (years): 67; Sex: M; Race: WHITE							
Investigations/ Neutrophil count increased/ ELEVATED NEUTROPHIL LEVEL	2020-10-07 (17)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	UNKNOWN
Subject ID: US3752256; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ ACUTE NON-INTRACTABLE HEADACHE	2020-09-02 (8)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Congenital, familial and genetic disorders/ Arnold-Chiari malformation/ ARNOLD-CHIARI MALFORMATION	2020-09-15 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Migraine without aura/ CHRONIC MIGRAINE WITHOUT AURA	2020-10-09 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752257; Age (years): 60; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer stage I/ STAGE 1 PROSTATE CANCER	2020-11-10 (49)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3752266; Age (years): 58; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-11-01 (40)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752283; Age (years): 75; Sex: M; Race: WHITE							
Nervous system disorders/ Hyposmia/ DIMINISHED SENSE OF SMELL	2020-09-30 (7)/ 2020-10-07 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-30 (7)/ 2020-10-07 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752283; Age (years): 75; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-09-30 (7)/ 2020-10-07 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3752290; Age (years): 65; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ POST-PROCEDURE PAIN FOLLOWING TOOTH EXTRACTION	2020-08-28 (2)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752332; Age (years): 50; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-05 (5)/ 2020-10-11 (11)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3752339; Age (years): 26; Sex: F; Race: WHITE							
Infections and infestations/ Uterine infection/ UTERINE INFECTION	2020-10-01 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3752339; Age (years): 26; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Uterine rupture/ UTERINE TEAR	2020-10-01 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Reproductive system and breast disorders/ Uterine haemorrhage/ HEAVY UTERINE BLEEDING	2020-10-01 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3752389; Age (years): 66; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-11-03 (35)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3752413; Age (years): 30; Sex: F; Race: WHITE							
Surgical and medical procedures/ Skin neoplasm excision/ EXCISION OF LEFT UPPER ARM MALIGNANT MELANOMA	2020-10-06 (5)/ 2020-10-06 (5)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3762033; Age (years): 82; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-11-12 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3762117; Age (years): 62; Sex: M; Race: WHITE							
Infections and infestations/ Furuncle/ BOIL ON BACK OF LEFT LEG	2020-09-14 (15)/ 2020-09-23 (24)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3762161; Age (years): 74; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-11-09 (41)/ 2020-11-15 (47)	Yes/ Yes/ No	3	Yes/2/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Dehydration/ [DIARRHEA WITH] DEHYDRATION	2020-11-09 (41)/ 2020-11-15 (47)	Yes/ Yes/ No	2	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3762161; Age (years): 74; Sex: M; Race: WHITE							
Infections and infestations/ Sepsis/ SEPSIS	2020-11-10 (42)/ Ongoing	Yes/ Yes/ No	3	Yes/2/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-11-10 (42)/ 2020-11-11 (43)	Yes/ Yes/ No	3	Yes/2/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	2020-11-10 (42)/ 2020-11-15 (47)	Yes/ Yes/ No	2	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	2020-11-10 (42)/ 2020-11-15 (47)	Yes/ Yes/ No	1	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Subject ID: US3762161; Age (years): 74; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyponatraemia/ ACUTE HYPONATREMIA	2020-11-10 (42)/ 2020-11-15 (47)	Yes/ Yes/ No	1	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Pneumonia/ LEFT UPPER LOBE PNEUMONIA	2020-11-10 (42)/ 2020-11-18 (50)	Yes/ Yes/ No	3	Yes/3 (2020-11-10/ 2020-11-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3762177; Age (years): 65; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ STOMACH PAINS	2020-10-27 (55)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3762230; Age (years): 74; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-10 00:00 (1)/ 2020-09-12 00:00 (3)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772006; Age (years): 54; Sex: F; Race: WHITE							
Surgical and medical procedures/ Endodontic procedure/ ROOT CANAL PROCEDURE	2020-08-25 (22)/ 2020-08-25 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772011; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-15 (7)/ 2020-09-20 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772015; Age (years): 52; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE (LEFT CALF)	2020-08-16 (12)/ 2020-08-16 (12)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772037; Age (years): 72; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE HYPOXIC RESPIRATORY FAILURE DUE TO COVID-19 INFECTION	2020-11-07 (61)/ 2020-11-12 (66)	Yes/ Yes/ No	4	Yes/3 (2020-11-08/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3772057; Age (years): 61; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS	2020-10-28 (42)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3772097; Age (years): 38; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS	2020-10-22 (39)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3772163; Age (years): 56; Sex: M; Race: WHITE							
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-09-10 (14)/ 2020-09-16 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Tooth infection/ TOOTH INFECTION	2020-10-08 (14)/ 2020-10-08 (14)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3782039; Age (years): 62; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS-POISON IVY	2020-09-01 (15)/ 2020-09-06 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3782057; Age (years): 50; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-17 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782065; Age (years): 52; Sex: M; Race: WHITE							
Eye disorders/ Retinal detachment/ RETINAL DETACHMENT	2020-10-08 (22)/ 2020-10-16 (30)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3782105; Age (years): 69; Sex: F; Race: WHITE							
Infections and infestations/ Cellulitis/ R ARM CELLULITIS	2020-10-27 (33)/ 2020-11-04 (41)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782128; Age (years): 64; Sex: F; Race: WHITE							
Infections and infestations/ Otitis externa/ BILATERAL OTITIS EXTERNA	2020-11-05 (38)/ 2020-11-11 (44)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3782130; Age (years): 40; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFICIENCY	2020-09-08 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3782141; Age (years): 38; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis streptococcal/ STREP PHARYNGITIS	2020-10-09 (9)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3782155; Age (years): 66; Sex: F; Race: WHITE							
Eye disorders/ Dry eye/ DRY EYES	2020-09-17 (10)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3782162; Age (years): 78; Sex: M; Race: WHITE							
Cardiac disorders/ Acute coronary syndrome/ ACUTE CORONARY SYNDROME	2020-09-21 (14)/ 2020-09-21 (14)	Yes/ Yes/ No	4	Yes/3 (2020-09-21/ 2020-09-24)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Cardiac disorders/ Angina pectoris/ CARDIAC CHEST PAIN	2020-10-14 (6)/ 2020-10-14 (6)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3792039; Age (years): 34; Sex: M; Race: WHITE							
Infections and infestations/ Pharyngitis/ THROAT INFECTION	2020-10-23 (19)/ 2020-10-30 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3792040; Age (years): 44; Sex: M; Race: WHITE							
Nervous system disorders/ Sciatica/ WORSENING OF SCIATIC PAIN	2020-09-15 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3792048; Age (years): 63; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-11-04 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-11-04 (23)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3792048; Age (years): 63; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-11-04 (23)/ 2020-11-10 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3792099; Age (years): 45; Sex: M; Race: ASIAN							
Infections and infestations/ Folliculitis/ FOLLICULITIS ON LOW BACK	2020-10-26 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3802008; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Periarthritis/ SCHEDULED LEFT FROZEN SHOULDER	2020-08-19 15:00 (2)/ 2020-08-19 16:00 (2)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Investigations/ Blood glucose decreased/ LOW BLOOD SUGAR	2020-09-04 (18)/ 2020-09-04 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802026; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Lyme disease/ LYME DISEASE	2020-11-04 (44)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3802082; Age (years): 32; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Dysmenorrhoea/ MENSTRUAL CRAMPS	2020-09-04 (5)/ 2020-09-05 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3802085; Age (years): 57; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Pityriasis rosea/ PITYRIASIS ROSEA	2020-09-26 08:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3802094; Age (years): 73; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Erythema/ REDNESS LEFT DELTOID	2020-09-11 (11)/ 2020-09-12 (12)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802097; Age (years): 26; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADANOPATHY LEFT SIDED SUBMENTAL NODES	2020-09-06 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Blood and lymphatic system disorders/ Lymphadenopathy/ LYMPHADENOPATHY LEFT SUPRACLAVICULAR NODE	2020-09-06 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3802113; Age (years): 66; Sex: F; Race: WHITE							
General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	2020-09-16 (15)/ 2020-09-18 (17)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3802148; Age (years): 53; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Foot fracture/ RIGHT FOOT FRACTURE	2020-09-17 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3802218; Age (years): 64; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Hiatus hernia/ PARAESOPHOGEAL HIATAL HERNIA WORSENING	2020-10-28 (16)/ 2020-11-05 (24)	Yes/ Yes/ No	2	Yes/3 (2020-10-28/ 2020-11-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812001; Age (years): 55; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-08-11 (9)/ 2020-09-03 (32)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812008; Age (years): 79; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ WORSENING DIABETES MELLITUS TYPE 2	2020-09-25 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812010; Age (years): 71; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-08-12 (10)/ 2020-08-14 (12)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Rash maculo-papular/ NON-URTICARIAL MACULOPAPULAR RASH TO LEFT UPPER ARM (BELOW INJECTION SITE)	2020-08-12 (10)/ 2020-08-14 (12)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812013; Age (years): 53; Sex: F; Race: WHITE							
Reproductive system and breast disorders/ Nipple exudate bloody/ LEFT NIPPLE BLEEDING	2020-09-03 (3)/ 2020-10-06 (36)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812022; Age (years): 70; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ RASH LEFT UPPER ARM [WHEAL]-URTICARIAL	2020-08-12 (9)/ 2020-08-16 (13)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812028; Age (years): 42; Sex: F; Race: WHITE							
Investigations/ Blood pressure increased/ ELEVATED BLOOD PRESSURE	2020-09-01 16:12 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3812043; Age (years): 67; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-08-12 (8)/ 2020-08-13 (9)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Renal and urinary disorders/ Nephrolithiasis/ LEFT KIDNEY STONE	2020-08-12 (8)/ 2020-08-19 (15)	Yes/ Yes/ No	4	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812066; Age (years): 48; Sex: M; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-10-20 (49)/ 2020-10-28 (57)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812071; Age (years): 70; Sex: F; Race: WHITE							
Nervous system disorders/ Cervical radiculopathy/ INTERMITTENT NERVE PAIN NECK	2020-09-02 02:00 (1)/ 2020-09-02 07:00 (1)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ WORSENING URINARY TRACT INFECTION	2020-09-08 (8)/ 2020-09-17 (17)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-26 (56)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812076; Age (years): 64; Sex: M; Race: WHITE							
Investigations/ Human rhinovirus test positive/ POSITIVE SWAB FOR HUMAN RHINOVIRUS	2020-11-09 (70)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812080; Age (years): 46; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-07 (6)/ 2020-09-14 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Dental caries/ DENTAL CARIES	2020-10-19 (48)/ 2020-10-19 (48)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812084; Age (years): 33; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-09-04 (2)/ 2020-09-04 (2)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812084; Age (years): 33; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPE (VASOVAGAL)	2020-09-04 (2)/ 2020-09-04 (2)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812091; Age (years): 72; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ RIGHT HALLUX DEGENERATIVE JOINT DISEASE	2020-09-14 (11)/ 2020-10-28 (55)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812096; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media/ OTITIS MEDIA-LEFT	2020-09-22 (21)/ 2020-09-28 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812096; Age (years): 43; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUSITIS (SINUS TENDERNESS)	2020-09-22 (21)/ 2020-09-28 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-18 (47)/ 2020-10-25 (54)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812098; Age (years): 67; Sex: M; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2020-08-28 (19)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Eye disorders/ Cataract/ WORSENING LEFT CATARACT	2020-10-15 (36)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812104; Age (years): 44; Sex: F; Race: WHITE							
Nervous system disorders/ Sciatica/ LEFT LOWER EXTREMITY SCIATICA PAIN FLARE-UP	2020-10-14 (36)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3812105; Age (years): 28; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Tooth impacted/ WISDOM TEETH IMPACTION	2020-10-29 (51)/ 2020-10-29 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812119; Age (years): 60; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth injury/ DAMAGED CROWN	2020-08-19 (9)/ 2020-08-21 (11)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812132; Age (years): 72; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ WORSENING GERD	2020-08-27 (17)/ 2020-09-08 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Psychiatric disorders/ Anxiety/ WORSENING ANXIETY	2020-08-27 (17)/ 2020-09-08 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS ON LEFT ARM	2020-09-09 09:00 (1)/ 2020-09-17 09:00 (9)	Yes/ Yes/ No	3	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Psychiatric disorders/ Anxiety/ WORSENING ANXIETY	2020-10-26 (49)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812132; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-10-26 (49)/ 2020-10-31 (54)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812147; Age (years): 72; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ WORSENING GERD	2020-10-22 (43)/ 2020-11-05 (57)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812158; Age (years): 38; Sex: M; Race: OTHER: (b) (6)							
Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	2020-08-19 (7)/ 2020-08-24 (12)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-08-19 (7)/ 2020-08-28 (16)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812158; Age (years): 38; Sex: M; Race: OTHER: (b) (6)							
Skin and subcutaneous tissue disorders/ Dermatitis/ GENERALIZED DERMATITIS	2020-09-12 (3)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ INTERMITTENT COUGH	2020-09-26 (17)/ 2020-10-03 (24)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812160; Age (years): 40; Sex: M; Race: WHITE							
Psychiatric disorders/ Anxiety/ ANXIETY	2020-11-10 (61)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812173; Age (years): 76; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ CHEST PAIN SECONDARY TO GASTROESOPHAGEAL REFLUX DISEASE EXACERBATION	2020-09-07 (25)/ 2020-09-07 (25)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812184; Age (years): 80; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Balanoposthitis/ BALANITIS	2020-09-02 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812192; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Pertussis/ BORDETELLA PERTUSSIS	2020-11-07 (54)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812194; Age (years): 48; Sex: F; Race: WHITE							
Investigations/ Glycosylated haemoglobin increased/ ELEVATED A1C	2020-10-26 (42)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812205; Age (years): 71; Sex: F; Race: WHITE							
Nervous system disorders/ Balance disorder/ UNSTEADINESS	2020-08-23 (6)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Ear and labyrinth disorders/ Vertigo positional/ BENIGN PAROXYSMAL POSITIONAL VERTIGO	2020-08-23 (6)/ 2020-09-12 (26)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE (RELATED TO BENIGN PAROXYSMAL POSITIONAL VERTIGO)	2020-08-23 (6)/ 2020-09-12 (26)	Yes/ Yes/ Yes	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812213; Age (years): 64; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Toothache/ TOOTHACHE	2020-08-22 (4)/ 2020-09-22 (35)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812219; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES LEFT HIP	2020-11-01 (48)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3812222; Age (years): 70; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Actinic keratosis/ WORSENING ACTINIC KERATOSIS-RIGHT ARM	2020-10-02 (16)/ 2020-10-13 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812222; Age (years): 70; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASAL CELL LESION ON FACE	2020-10-02 (16)/ 2020-11-19 (64)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Endocrine disorders/ Goitre/ ENLARGED THYROID	2020-10-27 (41)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812236; Age (years): 50; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	2020-09-19 00:00 (1)/ 2020-10-18 (31)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812236; Age (years): 50; Sex: F; Race: WHITE							
Metabolism and nutrition disorders/ Abnormal loss of weight/ UNINTENTIONAL WEIGHT LOSS (DOWN 6 LBS)	2020-10-02 (15)/ 2020-10-18 (31)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3812251; Age (years): 57; Sex: M; Race: WHITE							
Psychiatric disorders/ Rapid eye movement sleep behaviour disorder/ REM SLEEP BEHAVOIR DISORDER	2020-09-21 (29)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812253; Age (years): 53; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-09-29 (9)/ 2020-10-19 10:25 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812263; Age (years): 72; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ SYMPTOMIC COVID-19	2020-11-07 (46)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812267; Age (years): 29; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING ANXIETY	2020-10-27 (63)/ 2020-11-05 (72)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812271; Age (years): 58; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Lichen planus/ LICHEN PLANUS	2020-09-25 13:00 (1)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3812276; Age (years): 61; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-09-16 (21)/ 2020-10-20 (55)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Exostosis/ BONE SPUR-RIGHT KNEE	2020-10-16 (22)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812281; Age (years): 20; Sex: F; Race: WHITE							
Immune system disorders/ Hypersensitivity/ WORSENING ENVIRONMENTAL ALLERGIES	2020-09-20 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3812291; Age (years): 36; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Acne/ FACIAL ACNE	2020-10-01 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3812293; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Subcutaneous abscess/ LEFT AXILLARY ABSCESS	2020-09-06 (10)/ 2020-09-17 (21)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812294; Age (years): 27; Sex: F; Race: ASIAN							
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-09-10 (14)/ 2020-09-22 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DIFFICULTY BREATHING	2020-09-10 (14)/ 2020-09-22 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	2020-09-15 (19)/ 2020-09-22 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812301; Age (years): 41; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ MUSCLE STRAIN LOW BACK-RIGHT SIDE LOWER THORACIC REGION	2020-10-21 (24)/ 2020-11-03 (37)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3812306; Age (years): 46; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ TENDONITIS RIGHT FOOT FLARE-UP	2020-10-29 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3812308; Age (years): 88; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Gastrooesophageal reflux disease/ WORSENING GASTROESOPHAGEAL REFLUX DISEASE	2020-09-21 (20)/ 2020-09-22 (21)	Yes/ Yes/ No	2	No	NR/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812316; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Impetigo/ IMPETIGO	2020-10-12 (11)/ 2020-10-22 (21)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812318; Age (years): 61; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ INTERMITTENT HEADACHE	2020-10-02 (1)/ 2020-10-12 (11)	Yes/ Yes/ Yes	1	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Neck pain/ ACUTE NECK PAIN	2020-10-07 (6)/ Ongoing	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812335; Age (years): 49; Sex: M; Race: WHITE							
Blood and lymphatic system disorders/ Thrombocytopenia/ PRIMARY THROMBOCYTOPENIA	2020-10-12 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812335; Age (years): 49; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hypertriglyceridaemia/ NOCD OF HYPERTRIGLYCERIDEMIA	2020-10-12 (25)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3812336; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Vulvovaginal candidiasis/ VAGINAL CANDIDIASIS	2020-10-12 (25)/ 2020-10-14 (27)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3812344; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-09-26 (2)/ 2020-09-29 (5)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3812344; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Chest discomfort/ INTERMITTENT CHEST TIGHTNESS WITHOUT SHORTNESS OF BREATH	2020-09-26 (2)/ 2020-10-09 (15)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Musculoskeletal stiffness/ INTERMITTENT NECK STIFFNESS	2020-09-26 (2)/ 2020-10-20 05:30 (25)	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822003; Age (years): 65; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Salivary hypersecretion/ EXCESSIVE SALIVA ON SIDE NASAL SWAB COLLECTED	2020-08-04 11:30 (1)/ 2020-08-04 11:50 (1)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822003; Age (years): 65; Sex: M; Race: WHITE							
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2020-10-24 (54)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2020-10-24 (54)/ 2020-10-27 (57)	Yes/ Yes/ No	3	Yes/3 (2020-10-24/ 2020-10-27)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Cardiac disorders/ Pericarditis/ ACUTE PERICARDITIS	2020-11-12 (73)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2020-11-12/ 2020-11-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3822034; Age (years): 58; Sex: M; Race: WHITE							
Vascular disorders/ Orthostatic hypotension/ ORTHOSTATIC HYPOTENSION	2020-10-07 (35)/ 2020-10-18 (46)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822034; Age (years): 58; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	2020-10-07 (35)/ 2020-10-20 (48)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3822043; Age (years): 75; Sex: F; Race: WHITE							
Blood and lymphatic system disorders/ Lymphadenopathy/ ENLARGED LEFT AXILLARY LYMPH NODES	2020-09-05 (4)/ 2020-10-06 (35)	Yes/ Yes/ No	2	No	R/ R	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ B-cell small lymphocytic lymphoma/ SMALL LYMPHOCYTIC LYMPHOMA	2020-10-06 11:00 (34)/ Ongoing	Yes/ Yes/ No	3	Yes/6	R/ R	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3822045; Age (years): 78; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ SEVERE KNEE PAIN	2020-08-17 (11)/ 2020-08-17 (11)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3822138; Age (years): 70; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Lipoma/ LIPOMA ON LEFT ARM	2020-08-18 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3832010; Age (years): 30; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-08-21 (22)/ 2020-08-21 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: DEPRESSION
Subject ID: US3832020; Age (years): 76; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ STOMACH PAIN	2020-08-29 04:00 (1)/ 2020-08-31 11:00 (3)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832020; Age (years): 76; Sex: F; Race: WHITE							
Infections and infestations/ Otitis media acute/ ACUTE OF OTITIS MEDIA OF RIGHT EAR	2020-09-14 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Musculoskeletal and connective tissue disorders/ Spinal stenosis/ WORSENING OF SPINAL STENOSIS	2020-09-14 (18)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Respiratory, thoracic and mediastinal disorders/ Asthma/ ACUTE ASTHMA EXACERBATION	2020-09-14 (18)/ 2020-09-18 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832025; Age (years): 64; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	2020-09-11 (16)/ 2020-10-02 (37)	Yes/ Yes/ No	1	No	NR/ NA	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3832041; Age (years): 63; Sex: F; Race: WHITE							
Immune system disorders/ Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2020-09-18 (19)/ 2020-09-22 (23)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832043; Age (years): 29; Sex: F; Race: WHITE							
Infections and infestations/ Toxic shock syndrome/ SUSPECTED TOXIC SHOCK SYNDROME	2020-08-23 (22)/ 2020-08-25 (24)	Yes/ Yes/ No	3	Yes/3 (2020-08-23/ 2020-08-25)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-08-23 (22)/ 2020-08-30 (29)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832053; Age (years): 72; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING OF BILATERAL SHOULDER PAIN	2020-09-23 (24)/ 2020-11-03 (65)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832055; Age (years): 71; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Facial bones fracture/ CLOSED FRACTURE OF LATERAL WALL OF THE RIGHT ORBIT	2020-09-20 (12)/ 2020-09-23 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832055; Age (years): 71; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	2020-09-20 (12)/ 2020-09-23 (15)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT WAS HOSPITALIZED FOR A SYNCOPIAL EPISODE 20-23 SEP 2020. DURING HOSPITALIZATIO N, SUBJECT WAS GIVEN A DOSE OF SAMSCA TO CORRECT SODIUM LEVELS. SUBJECT D/C WITH SODIUM CHLORIDE RX. STABLE AT D/C

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832055; Age (years): 71; Sex: M; Race: WHITE							
Nervous system disorders/ Syncope/ SYNCOPAL EPISODE	2020-09-20 (12)/ 2020-09-23 (15)	Yes/ Yes/ No	3	Yes/3 (2020-09-20/ 2020-09-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832060; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS	2020-09-24 (25)/ 2020-09-24 (25)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT REPORTED GETTING CORTISONE INJECTIONS IN BOTH KNEES FOR WORSENING OF OSTEOARTHRITIS . SUBJECT REPORTS THAT THE INJECTIONS HAVE HELPED. SUBJECT TO CONTINUE IN

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832060; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS	2020-10-24 (55)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832063; Age (years): 70; Sex: M; Race: WHITE							
Infections and infestations/ Nasopharyngitis/ COMMON COLD	2020-10-04 (35)/ 2020-10-10 (41)	Yes/ Yes/ No	2	No	NR/ NA	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832069; Age (years): 56; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ MOLAR TOOTH DECAY	2020-10-21 (51)/ 2020-10-21 (51)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3832078; Age (years): 57; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-11-05 (66)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832079; Age (years): 59; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-09-04 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832082; Age (years): 53; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Animal bite/ CAT BITE	2020-09-05 (5)/ 2020-09-12 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ WORSENING OF HERNIATED DISC	2020-10-21 (51)/ 2020-10-21 (51)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832088; Age (years): 59; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY DERMATITIS	2020-09-11 (11)/ 2020-09-26 (26)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832097; Age (years): 40; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ POST-OPERATIVE PAIN (RIGHT SHOULDER)	2020-09-23 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832103; Age (years): 81; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-10 (9)/ 2020-09-10 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: INCREASED DOSE OF LISINOPRIL FROM 10 MG TO 20 MG

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832125; Age (years): 74; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-28 (25)/ 2020-10-06 (33)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT INCREASED DOSE OF CARVEDILOL FROM 6.25 MG TO 12.5 MG. SUBJECT'S BLOOD PRESSURE WAS TAKEN DURING CLINIC VISIT DAY 57 AND WAS ASSESSED AS ABNORMAL NCS. AE RESOLVED WITH SEQUELAE.

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832136; Age (years): 49; Sex: F; Race: WHITE							
Infections and infestations/ Cat scratch disease/ LEFT ARM LYMPHORETICULOSIS	2020-08-19 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832137; Age (years): 51; Sex: F; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-09-22 (14)/ 2020-09-30 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT WAS PRESCRIBED MEDICATION AT PCP VISIT
Subject ID: US3832138; Age (years): 37; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-09-17 (8)/ 2020-09-23 (14)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832146; Age (years): 57; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-09-12 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832148; Age (years): 70; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tendon rupture/ EXTENSOR TENDON RUPTURE	2020-09-18 (9)/ 2020-09-18 (9)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3832168; Age (years): 49; Sex: M; Race: WHITE							
Infections and infestations/ Abscess limb/ LEFT LEG ABSCESS	2020-08-22 (12)/ 2020-10-12 (63)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832177; Age (years): 65; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING OF ANXIETY	2020-09-28 (20)/ 2020-09-30 (22)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832179; Age (years): 87; Sex: F; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-10-05 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832185; Age (years): 50; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ RIGHT ARM SPRAIN.	2020-08-13 18:00 (1)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Subject ID: US3832195; Age (years): 70; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Pneumonia aspiration/ ASPIRATION PNEUMONIA	2020-11-05 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832197; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Suspected COVID-19/ COVID LIKE ILLNESS	2020-10-29 (45)/ 2020-11-03 (50)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832202; Age (years): 39; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Irritable bowel syndrome/ WORSENING OF IRRITABLE BOWEL SYNDROME	2020-09-24 (9)/ 2020-10-13 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832202; Age (years): 39; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ COPD EXACERBATION	2020-10-07 (22)/ 2020-10-13 (28)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3832206; Age (years): 67; Sex: M; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ COPD EXACERBATION	2020-09-01 (16)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832212; Age (years): 41; Sex: F; Race: WHITE							
Psychiatric disorders/ Attention deficit hyperactivity disorder/ ATTENTION DEFICIT DISORDER	2020-08-22 (5)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832220; Age (years): 66; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-09-29 (14)/ 2020-10-03 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Stomatitis/ MOUTH SORES SECONDARY TO DRUG REACTION	2020-10-02 (17)/ 2020-10-05 (20)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3832222; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS - FACE	2020-08-20 15:00 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832242; Age (years): 43; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ WORSENING OF ANXIETY	2020-09-17 (28)/ 2020-09-17 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT HAD HISTORY OF ANXIETY AND STARTED MEDICATION TO HELP WITH SYMPTOMS. SUBJECT REPORTS THAT MEDICATION HAS RESOLVED SYMPTOMS, BUT WILL CONTINUE TAKING MEDICATION AS PRESCRIBED.

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832250; Age (years): 28; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-02 (40)/ 2020-10-20 (58)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: STARTED PHENEGAN
Subject ID: US3832253; Age (years): 56; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Muscle strain/ LOWER BACK STRAIN	2020-11-02 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3832265; Age (years): 72; Sex: M; Race: WHITE							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-09-04 (4)/ 2020-09-14 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3832265; Age (years): 72; Sex: M; Race: WHITE							
Psychiatric disorders/ Insomnia/ INSOMNIA	2020-09-04 (4)/ 2020-09-22 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT REPORTS THAT THE MEDICATION STARTED HAS HELPED TO MANAGE HIS INSOMNIA.
Subject ID: US3842008; Age (years): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Muscle strain/ MUSCLE STRAIN, BACK	2020-09-08 (9)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3842042; Age (years): 51; Sex: F; Race: OTHER: (b) (6)							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-19 (29)/ 2020-10-27 (37)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852002; Age (years): 61; Sex: F; Race: WHITE							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-09-22 (8)/ 2020-10-05 (21)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852023; Age (years): 78; Sex: M; Race: WHITE							
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2020-09-05 (12)/ 2020-09-11 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Injury, poisoning and procedural complications/ Post-traumatic pain/ UPPER BACK PAIN BELOW SHOULDER BLADES FROM RECENT MVA	2020-11-03 (43)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Injury, poisoning and procedural complications/ Road traffic accident/ MVA	2020-11-03 (43)/ 2020-11-03 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852025; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDER PAIN	2020-10-01 (11)/ 2020-10-10 (20)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852032; Age (years): 76; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tooth fracture/ TOOTH CRACKED	2020-08-31 (6)/ 2020-09-04 (10)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3852055; Age (years): 61; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ SWOLLEN/TENDER RIGHT HAND, 4TH MCP JOINT	2020-09-01 (5)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852069; Age (years): 68; Sex: F; Race: WHITE							
Nervous system disorders/ Headache/ HEADACHE	2020-09-23 (24)/ 2020-09-26 (27)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-09-23 (24)/ 2020-09-26 (27)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-23 (24)/ 2020-10-01 (32)	Yes/ Yes/ No	3	No	NR/ NR	DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852076; Age (years): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-11-04 (31)/ 2020-11-11 (38)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852084; Age (years): 39; Sex: F; Race: WHITE							
Infections and infestations/ Herpes simplex/ HERPES SIMPLEX OUTBREAK	2020-10-12 (12)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3852115; Age (years): 29; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Stress fracture/ LEFT ELBOW HAIRLINE FRACTURE	2020-10-12 (4)/ 2020-10-12 (4)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852129; Age (years): 64; Sex: F; Race: WHITE							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Melanocytic naevus/ MOLE IRRITATION	2020-09-22 (13)/ 2020-09-22 (13)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3852133; Age (years): 51; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ UPPER ABDOMINAL PAIN	2020-09-20 (13)/ 2020-09-20 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3852133; Age (years): 51; Sex: M; Race: WHITE							
Nervous system disorders/ Paraesthesia/ RIGHT ARM PARESTHESIA	2020-09-20 (13)/ 2020-09-20 (13)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3852164; Age (years): 31; Sex: F; Race: WHITE							
Infections and infestations/ Sinusitis/ SINUS INFECTION	2020-09-27 (18)/ 2020-10-05 (26)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3852196; Age (years): 56; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Psychiatric disorders/ Anxiety/ WORSENING ANXIETY	2020-10-26 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Vascular disorders/ Hypertension/ HYPERTENSION	2020-11-11 (24)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862003; Age (years): 71; Sex: M; Race: WHITE							
Eye disorders/ Retinal detachment/ LEFT EYE RETINAL DETACHMENT	2020-09-04 (25)/ 2020-09-11 (32)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3862021; Age (years): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Cardiac disorders/ Myocardial infarction/ INFEROLATERAL STEMI	2020-10-04 00:45 (20)/ 2020-10-07 (24)	Yes/ Yes/ No	4	Yes/2/3 (2020-10-04/ 2020-10-07)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3862024; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Gingivitis/ GINGIVITIS	2020-09-20 (6)/ 2020-10-02 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862028; Age (years): 32; Sex: F; Race: WHITE							
Psychiatric disorders/ Anxiety/ SITUATIONAL ANXIETY	2020-08-24 (7)/ 2020-08-31 (14)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862035; Age (years): 62; Sex: F; Race: MULTIPLE: (b) (6)							
Blood and lymphatic system disorders/ Lymphadenopathy/ IPSILATERAL - LEFT AXILLARY LYMPADENOPATHY NOTED ON ULTRASOUND	2020-09-30 (17)/ Ongoing	Yes/ Yes/ No	1	No	R/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862036; Age (years): 65; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ EXACERBATION OF RIGHT ANKLE SPRAIN	2020-08-20 03:00 (1)/ 2020-09-09 21:00 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862075; Age (years): 74; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2020-10-14 (21)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862112; Age (years): 71; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	2020-10-01 19:00 (2)/ 2020-10-22 18:00 (23)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3862140; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Urinary tract infection/ UTI	2020-10-08 (3)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862159; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ UNCONTROLLED HYPERTENSION	2020-09-14 (6)/ 2020-10-09 (31)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Endocrine disorders/ Thyroid cyst/ BENIGN THYROID CYST	2020-09-17 (9)/ 2020-11-08 (61)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3862173; Age (years): 73; Sex: F; Race: WHITE							
Gastrointestinal disorders/ Hiatus hernia/ SLIDING HIATAL HERNIA	2020-09-29 (19)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862224; Age (years): 64; Sex: M; Race: ASIAN							
Infections and infestations/ Otitis externa/ BILATERAL OTITIS EXTERNA	2020-11-09 (20)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3862257; Age (years): 42; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis allergic/ ALLERGIC DERMATITS	2020-10-03 (5)/ 2020-10-09 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3862262; Age (years): 68; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION NEW ONSET	2020-10-05 (7)/ 2020-10-05 (7)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872018; Age (years): 66; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	2020-10-09 (39)/ 2020-10-12 (42)	Yes/ Yes/ No	3	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3872090; Age (years): 63; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA UNSPECIFIED TYPE	2020-08-11 (5)/ 2020-09-14 (39)	Yes/ Yes/ No	3	Yes/3 (2020-08-18/ 2020-08-22)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Enteritis/ ILEITIS	2020-08-11 (5)/ 2020-09-14 (39)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872118; Age (years): 36; Sex: F; Race: MULTIPLE:				(b) (6)			
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2020-11-15 (69)/ 2020-11-15 (69)	Yes/ Yes/ No	4	Yes/3 (2020-11-15/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3872184; Age (years): 61; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diverticulum/ DIVERTICULOSIS	2020-11-13 (60)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Large intestine polyp/ COLON POLYP	2020-11-13 (60)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3872197; Age (years): 63; Sex: M; Race: WHITE							
Nervous system disorders/ Small fibre neuropathy/ SMALL FIBER MOTOR NEUROPATHY BILATERAL LOWER EXTREMITIES	2020-09-08 (26)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872197; Age (years): 63; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Tendonitis/ RIGHT HIP ABDUCTOR TENDONITIS	2020-09-08 (26)/ 2020-10-16 (64)	Yes/ Yes/ No	3	No	NR/ NA	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872198; Age (years): 65; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ BODY RASH	2020-10-31 (46)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3872202; Age (years): 65; Sex: F; Race: WHITE							
Infections and infestations/ Tinea infection/ RINGWORM	2020-10-30 (78)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3872235; Age (years): 37; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-12 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872272; Age (years): 50; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Axillary pain/ LEFT AXILLARY TENDERNESS	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site induration/ INJECTION SITE INDURATION	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872272; Age (years): 50; Sex: F; Race: OTHER: (b) (6)							
General disorders and administration site conditions/ Injection site pain/ INJECTION SITE TENDERNESS	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Injection site warmth/ INJECTION SITE WARMTH	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Joint range of motion decreased/ LEFT UPPER ARM LIMITED RANGE OF MOTION	2020-08-31 (8)/ Ongoing	Yes/ Yes/ Yes	1	No	R/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3872318; Age (years): 62; Sex: M; Race: WHITE							
Psychiatric disorders/ Completed suicide/ SUICIDE	2020-09-16 (21)/ 2020-09-16 (21)	Yes/ Yes/ No	4	Yes/1	NR/ NR	NOT APPLICABLE/ NONE	FATAL
Subject ID: US3872366; Age (years): 58; Sex: F; Race: WHITE							
Infections and infestations/ Bronchitis/ BRONCHITIS	2020-10-06 (39)/ 2020-10-10 (43)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3872416; Age (years): 36; Sex: M; Race: MULTIPLE: (b) (6)							
General disorders and administration site conditions/ Chest discomfort/ CHEST DISCOMFORT	2020-10-12 (41)/ 2020-10-12 (41)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3882014; Age (years): 70; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-09-23 12:00 (1)/ 2020-09-29 12:00 (7)	No/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3882037; Age (years): 75; Sex: M; Race: ASIAN							
Infections and infestations/ Urinary tract infection/ UTI	2020-11-18 (13)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERING/ RESOLVING
Subject ID: US3892010; Age (years): 75; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ WORSENING OF BENIGN PROSTATIC HYPERPLASIA	2020-09-24 (4)/ 2020-09-25 (5)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	2020-11-22 (63)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3892017; Age (years): 31; Sex: M; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-15 (45)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	
Subject ID: US3892018; Age (years): 28; Sex: F; Race: WHITE							
Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2020-11-14 (44)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3892020; Age (years): 70; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ HERPES ZOSTER - RIGHT HIP	2020-08-31 (5)/ 2020-10-01 (36)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SCAR RIGHT HIP

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Unsolicited Medically-Attended Adverse Events
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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relationship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3892025; Age (years): 50; Sex: F; Race: WHITE							
Infections and infestations/ Body tinea/ TINEA CORPORIS	2020-10-02 (8)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	
Subject ID: US3892026; Age (years): 55; Sex: M; Race: WHITE							
Cardiac disorders/ Tachycardia/ TACHYCARDIA	2020-09-26 10:00 (1)/ 2020-09-26 22:00 (2)	Yes/ Yes/ No	2	No	R/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3892055; Age (years): 30; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection/ ACUTE RESPIRATORY INFECTION	2020-11-15 (38)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3892070; Age (years): 33; Sex: M; Race: WHITE							
Reproductive system and breast disorders/ Prostatitis/ PROTATITIS	2020-09-27 (18)/ 2020-10-07 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3892075; Age (years): 36; Sex: F; Race: WHITE							
Infections and infestations/ Respiratory tract infection/ ACUTE RESPIRATORY INFECTION	2020-11-09 (32)/ 2020-11-15 (38)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3892081; Age (years): 36; Sex: F; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash papular/ ERYTHEMA LEFT ARM, PAPULAR, CONFLUENT, NON-URTICARIAL	2020-09-22 (9)/ 2020-09-26 (13)	Yes/ Yes/ No	2	No	R/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3902016; Age (years): 77; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES ON LEFT THIGH	2020-09-08 (7)/ 2020-09-20 (19)	Yes/ Yes/ No	1	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3902030; Age (years): 66; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Urticaria/ HIVES	2020-09-05 (3)/ 2020-09-21 (19)	Yes/ Yes/ No	1	No	R/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3902060; Age (years): 61; Sex: M; Race: WHITE							
Ear and labyrinth disorders/ Ear pain/ RIGHT EARACHE	2020-10-27 (14)/ 2020-10-30 (17)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3902070; Age (years): 70; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Trigger finger/ TRIGGER FINGER LEFT HAND	2020-09-22 (12)/ 2020-09-22 (12)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3902106; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	2020-10-23 (8)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3902130; Age (years): 67; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Dental caries/ DENTAL CAVITY	2020-11-06 (22)/ 2020-11-06 (22)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912012; Age (years): 76; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Melaena/ MELENA (BLACK STOOL)	2020-11-15 (53)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912024; Age (years): 72; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Intestinal perforation/ BOWEL PERFORATION	/ 2020-11-08 (73)	Yes/ Yes/ No	3	Yes/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912024; Age (years): 72; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Flank pain/ FLANK PAIN (LEFT)	2020-11-03 (41)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE	2020-11-12 (50)/ Ongoing	Yes/ Yes/ No	3	Yes/2/3 (2020-11-03/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912083; Age (years): 69; Sex: F; Race: ASIAN							
Injury, poisoning and procedural complications/ Bone contusion/ BRUISED STERNUM	2020-10-10 (11)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912091; Age (years): 68; Sex: M; Race: WHITE							
General disorders and administration site conditions/ Inflammation/ WORSENING OF INFLAMMATION RIGHT SHOULDER	2020-09-10 (8)/ 2020-10-07 (35)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912114; Age (years): 74; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	2020-10-30 (57)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Humerus fracture/ BROKEN RIGHT HUMERUS (RELATED TO FALL)	2020-10-30 (57)/ 2020-11-10 (68)	Yes/ Yes/ No	4	Yes/3 (2020-11-10/ 2020-11-11)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912116; Age (years): 58; Sex: M; Race: ASIAN							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS-BILATERAL UPPER EXTREMITIES	2020-10-03 (2)/ Ongoing	Yes/ Yes/ Yes	3	No	R/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Gastrointestinal disorders/ Vomiting/ EMESIS	2020-10-16 (15)/ 2020-10-18 (17)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Investigations/ Aspartate aminotransferase increased/ ELEVATED LIVER ENZYMES (AST)	2020-10-17 (16)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	UNKNOWN

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912116; Age (years): 58; Sex: M; Race: ASIAN							
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2020-10-17 (16)/ 2020-10-17 (16)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2020-10-17 (16)/ 2020-10-17 (16)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3912120; Age (years): 53; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ WORSENING OF SEASONAL ALLERGY CHEST CONGESTION	2020-10-15 (10)/ 2020-10-18 (13)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912131; Age (years): 51; Sex: F; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABSCESSED TOOTH	2020-09-21 (14)/ 2020-10-07 (30)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3912173; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Metabolism and nutrition disorders/ Glucose tolerance impaired/ WORSENING OF PRE-DIABETES	2020-11-09 (27)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912191; Age (years): 35; Sex: M; Race: WHITE							
Infections and infestations/ Tooth abscess/ ABSCESSED TOOTH	2020-10-13 (26)/ 2020-10-19 (32)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912200; Age (years): 46; Sex: M; Race: WHITE							
Psychiatric disorders/ Depression/ WORSENING DEPRESSION	2020-10-04 (13)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3912205; Age (years): 47; Sex: M; Race: ASIAN							
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2020-10-18 (26)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912212; Age (years): 36; Sex: M; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING RIGHT SHOULDER PAIN	2020-11-05 (15)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912242; Age (years): 56; Sex: F; Race: WHITE							
Infections and infestations/ Herpes zoster/ SHINGLES	2020-10-18 (7)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3912242; Age (years): 56; Sex: F; Race: WHITE							
Vascular disorders/ Achenbach syndrome/ ACHENBACH SYNDROME	2020-11-05 (25)/ 2020-11-07 (27)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3922009; Age (years): 70; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Ligament sprain/ TWISTED RIGHT KNEE(DUE TO OSTEOARTHRITIS)	2020-09-12 (25)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3922025; Age (years): 66; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-24 (30)/ 2020-10-24 (30)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-24 (30)/ 2020-10-24 (30)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

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Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3922033; Age (years): 68; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Procedural pain/ PAIN DUE TO BREAST REDUCTION(BILATERAL)	2020-10-22 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3922044; Age (years): 69; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY BILATERAL LOWER LEGS	2020-09-15 (20)/ 2020-09-23 (28)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3922059; Age (years): 73; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Contusion/ HEAD CONTUSION	2020-09-08 (9)/ 2020-09-22 (23)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	2020-10-07 (6)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3922114; Age (years): 34; Sex: M; Race: WHITE							
Vascular disorders/ Hypertension/ HYPERTENSION	2020-10-16 (2)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932018; Age (years): 47; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Rash/ RASH ON BILATERAL LEGS	2020-10-10 (17)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3932077; Age (years): 29; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Abdominal pain upper/ SEVERE STOMACH CRAMPING	2020-11-06 (36)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	
Gastrointestinal disorders/ Nausea/ INTERMITTENT NAUSEA	2020-11-06 (36)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2020-11-11/ 2020-11-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3942018; Age (years): 67; Sex: M; Race: WHITE							
Skin and subcutaneous tissue disorders/ Precancerous skin lesion/ PRE CANCEROUS MOLES REMOVED	2020-10-13 (20)/ 2020-10-13 (20)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Surgical and medical procedures/ Skin neoplasm excision/ BASAL CELL CARCINOMA REMOVAL ON LEFT BACK SHOULDER REMOVAL	2020-10-27 (34)/ 2020-10-27 (34)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3942121; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2020-10-26 (33)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3942150; Age (years): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Infections and infestations/ Kidney infection/ KIDNEY INFECTION	2020-10-31 (20)/ 2020-11-06 (26)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3952100; Age (years): 39; Sex: F; Race: WHITE							
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	2020-09-22 (6)/ 2020-09-22 (6)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3952104; Age (years): 67; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Hip fracture/ HIP FRACTURE	2020-10-05 (19)/ 2020-10-08 (22)	Yes/ Yes/ No	3	Yes/3 (2020-10-07/ 2020-10-12)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3962028; Age (years): 64; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Back pain/ UPPER BACK PAIN	2020-10-04 (10)/ 2020-10-17 (23)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962028; Age (years): 64; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASM IN UPPER BACK	2020-10-06 (12)/ 2020-10-10 (16)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3962063; Age (years): 57; Sex: F; Race: WHITE							
Injury, poisoning and procedural complications/ Tendon rupture/ TORN TENDON LEFT ANKLE	2020-10-02 (2)/ 2020-10-31 (31)	Yes/ Yes/ No	4	Yes/3 (2020-10-30/ 2020-10-31)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3962072; Age (years): 63; Sex: M; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ EXACERBATION OF ATRIAL FIBRILLATION	2020-11-04 (31)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3962073; Age (years): 36; Sex: M; Race: WHITE							
Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ EXACERBATION OF DIABETES - TYPE II	2020-10-01 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3962075; Age (years): 68; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2020-10-20 (15)/ 2020-11-03 (29)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3972001; Age (years): 48; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2020-08-21 08:58 (1)/ 2020-08-21 13:25 (1)	No/ Yes/ No	1	No	NA/ NA	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED WITH SEQUELAE: N/A
Subject ID: US3972045; Age (years): 62; Sex: M; Race: WHITE							
Gastrointestinal disorders/ Diabetic gastroparesis/ DIABETIC GASTRO PARESIS	2020-10-21 14:00 (28)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3972064; Age (years): 69; Sex: F; Race: MULTIPLE: (b) (6)							
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE EXACERBATION	2020-09-02 06:45 (2)/ 2020-09-05 17:00 (6)	Yes/ Yes/ No	2	Yes/3 (2020-09-02/ 2020-09-05)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3972064; Age (years): 69; Sex: F; Race: MULTIPLE:						(b) (6)	
Gastrointestinal disorders/ Large intestine polyp/ COLON POLYP	2020-10-06 (7)/ 2020-10-07 (8)	Yes/ Yes/ No	1	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3972123; Age (years): 55; Sex: F; Race: WHITE							
Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASMS IN NECK	2020-09-26 (19)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3972225; Age (years): 22; Sex: F; Race: WHITE							
Infections and infestations/ COVID-19/ COVID 19 INFECTION	2020-10-15 (4)/ Ongoing	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3982002; Age (years): 39; Sex: M; Race: WHITE							
Infections and infestations/ Sinusitis/ BILATERAL SINUSITIS	2020-09-29 (8)/ 2020-10-09 (18)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982110; Age (years): 29; Sex: M; Race: WHITE							
Injury, poisoning and procedural complications/ Muscle strain/ LEFT ARM STRAIN	2020-09-11 (8)/ 2020-09-14 (11)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	2020-10-05 (4)/ 2020-10-15 (14)	Yes/ Yes/ No	2	No	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3982132; Age (years): 52; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Injury, poisoning and procedural complications/ Skin laceration/ LACERATION LEFT 4TH DIGIT OF HAND	2020-09-11 (4)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3982141; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Surgical and medical procedures/ Dental operation/ DENTAL EXTRACTIONS	2020-09-24 (16)/ 2020-09-24 (16)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3982147; Age (years): 52; Sex: M; Race: WHITE							
Infections and infestations/ Otitis externa/ OTITIS EXTERNA	2020-11-03 (22)/ Ongoing	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3982216; Age (years): 44; Sex: M; Race: MULTIPLE:						(b) (6)	
Infections and infestations/ Pharyngitis/ PHARYNGITIS	2020-10-08 (18)/ 2020-10-13 (23)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3982272; Age (years): 69; Sex: F; Race: WHITE							
Cardiac disorders/ Atrial fibrillation/ NEW ONSET ATRIAL FIBRILLATION	2020-10-20 (8)/ 2020-10-27 (15)	Yes/ Yes/ No	3	Yes/3 (2020-10-20/ 2020-10-22)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Subject ID: US3992014; Age (years): 21; Sex: F; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Rash/ RASH ARMPITS	2020-10-19 19:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992014; Age (years): 21; Sex: F; Race: ASIAN							
Skin and subcutaneous tissue disorders/ Urticaria/ ITCHY HIVES ON ARMS	2020-10-19 19:00 (1)/ Ongoing	Yes/ Yes/ Yes	2	No	R/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3992016; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2020-10-01 (10)/ Ongoing	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
General disorders and administration site conditions/ Chills/ CHILLS	2020-10-01 (10)/ 2020-10-07 (16)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	2020-10-01 (10)/ 2020-10-09 (18)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992016; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
Gastrointestinal disorders/ Nausea/ NAUSEA	2020-10-01 (10)/ 2020-10-09 (18)	Yes/ Yes/ Yes	3	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	2020-10-02 (11)/ 2020-10-07 (16)	Yes/ Yes/ No	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	2020-10-02 (11)/ 2020-10-09 (18)	Yes/ Yes/ No	1	No	R/ R	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Nervous system disorders/ Headache/ HEADACHES	2020-10-03 (12)/ 2020-10-07 (16)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992016; Age (years): 37; Sex: F; Race: BLACK OR AFRICAN AMERICAN							
General disorders and administration site conditions/ Fatigue/ FATIGUE	2020-10-03 (12)/ 2020-10-09 (18)	Yes/ Yes/ Yes	3	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
General disorders and administration site conditions/ Pain/ BODY ACHES	2020-10-03 (12)/ 2020-10-09 (18)	Yes/ Yes/ Yes	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-10-05 (14)/ 2020-10-09 (18)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Subject ID: US3992052; Age (years): 25; Sex: F; Race: ASIAN							
Infections and infestations/ Bacterial vaginosis/ BACTERIAL VAGINOSIS	2020-10-27 (27)/ 2020-11-06 (37)	Yes/ Yes/ No	2	No	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Unsolicited Medically-Attended Adverse Events
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. [1]	SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken with IP/ Other Action Taken	Outcome
Subject ID: US3992113; Age (years): 37; Sex: M; Race: BLACK OR AFRICAN AMERICAN							
Nervous system disorders/ Headache/ HEADACHE	2020-11-03 (16)/ 2020-11-09 (22)	Yes/ Yes/ Yes	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORETHROAT	2020-11-03 (16)/ 2020-11-09 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE	2020-11-03 (16)/ 2020-11-09 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	2020-11-03 (16)/ 2020-11-09 (22)	Yes/ Yes/ No	1	No	NR/ NR	DOSE NOT CHANGED/ NONE	RECOVERED/ RESOLVED

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Listing 16.2.7.13
Unsolicited Medically-Attended Adverse Events
Safety Set

TEAE = Treatment-Emergent Adverse Event; MAAE = Medically-Attended Adverse Event; AR = Adverse Reaction; SAE = Serious Adverse Event; IP = Investigational Product; SP = Study Procedure.
Relative day is defined as days from the most recent injection date.
MedDRA version 23.0.
[1] Sev. = Severity, 1 = Grade 1/Mild, 2 = Grade 2/Moderate, 3 = Grade 3/Severe, 4 = Grade 4.
[2] 1 = Death, 2 = Life threatening, 3 = Requires inpatient or prolongation of existing Hospitalization (Hospital Admission Date/ Hospital Discharge Date), 4 = Persistent or significant disability or incapacity, 5 = Congenital anomaly or birth defect, 6 = Other medically important event.
[3] R = Related, NR = Not Related, NA = Not Applicable.

Listing 16.2.12
Death Listing
Safety Set

Treatment Group: Placebo

Subject ID	Age (years)	Sex	Race	Ethnicity	BMI (kg/m²)	Risk Factors for Severe COVID-19	Baseline SARS-CoV-2 Status	Date of Death	Main Cause of Death/ Cause Specified	Was Autopsy Performed?
US3032204	54	M	WHITE	NOT HISPANIC OR LATINO	28.6	Diabetes	Negative	2020-11-16	UNKNOWN	UNK
US3082269	75	M	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	25.3		Negative	2020-10-03	ADVERSE EVENT	UNK
US3272070	74	M	WHITE	NOT HISPANIC OR LATINO	36.7	Significant Cardiac Disease, Diabetes	Negative	2020-10-01	ADVERSE EVENT	UNK
US3322199	64	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	31.4		Negative	2020-11-16	ADVERSE EVENT	UNK
US3342256	43	M	UNKNOWN	NOT HISPANIC OR LATINO	29.0		Negative	2020-09-20	ADVERSE EVENT	UNK
US3432295	83	M	WHITE	NOT HISPANIC OR LATINO	23.4		Negative	2020-10-02	ADVERSE EVENT	UNK

Listing 16.2.12
Death Listing
Safety Set

Treatment Group: mRNA-1273

Subject ID	Age (years)	Sex	Race	Ethnicity	BMI (kg/m²)	Risk Factors for Severe COVID-19	Baseline SARS-CoV-2 Status	Date of Death	Main Cause of Death/ Cause Specified	Was Autopsy Performed?
US3512042	78	M	WHITE	NOT HISPANIC OR LATINO	22.2		Negative	2020-09-01	ADVERSE EVENT	UNK
US3752173	77	M	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	28.1		Negative	2020-11-01	ADVERSE EVENT	UNK
US3872318	62	M	WHITE	NOT HISPANIC OR LATINO	27.9		Negative	2020-09-16	ADVERSE EVENT	N
US3962094	56	F	WHITE	NOT HISPANIC OR LATINO	43.6	Severe Obesity	Negative	2020-10-15	OTHER/ HEAD TRAUMA	N