

US3552024 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:38:44

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US3552024

Form: Participant Creation

Generated On: 26 Nov 2020 09:38:44

[Participant ID](#)

US3552024

[mRNA-1273-P301 Completion Guidelines](#)

US3552024

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3552024

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:38:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3552024

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:38:44

Were any significant conditions reported?

Yes ☒

No ☐

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN JUN 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

Condition	BILATERAL GLAUCOMA
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

Condition	CATARACT RIGHT EYE
Start date (dd MMM yyyy)	UN DEC 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

Condition	CATARACT LENS IMPLANT IN RIGHT EYE
Start date (dd MMM yyyy)	UN DEC 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	11 JUN 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

Condition	R EYE LASER SURGERY FOR CATARACT
Start date (dd MMM yyyy)	UN DEC 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:00 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:00
Height (<i>xxx.x</i>)	71 in
Weight (<i>xxx.x</i>)	191.4 lb
BMI (<i>xxx.x</i>)	26.75070 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552024

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐
	No ☒
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐
	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐
	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐
	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐
	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☒
	No ☐
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐
	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐
	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐
	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐
	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐
	No ☒
Other	Yes ☐
	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3552024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103592

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:44

Height	ND - Not Done
Weight	ND - Not Done

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:06
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3552024

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 AUG 2020

What was the treatment time? (00:00-23:59) 12:36 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 12:36

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3552024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

13 AUG 2020

Collection time (*00:00-23:59*)

11:45 (24 HR)

Collection date and time (derived)

13 AUG 2020 11:45

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:44

Collection date (<i>dd MMM yyyy</i>)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:49	13 AUG 2020 11:49
Nasopharyngeal Swab 2	No		

US3552024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

13 AUG 2020 13:10

PC Open Date & Time

13 AUG 2020 12:56

PC Close Date & Time

13 AUG 2020 15:26

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	13 AUG 2020 16:24
PC Open Date & Time	13 AUG 2020 16:21
PC Close Date & Time	14 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

14 AUG 2020 13:01

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

15 AUG 2020 12:06

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp 16 AUG 2020 12:21

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

17 AUG 2020 12:04

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

18 AUG 2020 12:11

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

19 AUG 2020 12:11

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 13:11

PC Open Date & Time

13 AUG 2020 12:56

PC Close Date & Time

13 AUG 2020 15:26

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 16:26

PC Open Date & Time

13 AUG 2020 16:21

PC Close Date & Time

14 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 13:02

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:06

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:22

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:05

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:11

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 12:12

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 13:12
PC Open Date & Time	13 AUG 2020 12:56
PC Close Date & Time	13 AUG 2020 15:26

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 16:27
PC Open Date & Time	13 AUG 2020 16:21
PC Close Date & Time	14 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

Yes ☐	
PC Time stamp	14 AUG 2020 13:03
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

Yes ☐	
PC Time stamp	15 AUG 2020 12:07
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

Yes ☐	
PC Time stamp	16 AUG 2020 12:23
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

Yes ☐	
PC Time stamp	17 AUG 2020 12:05
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

Yes ☐	
PC Time stamp	18 AUG 2020 12:12
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

Yes ☐	
PC Time stamp	19 AUG 2020 12:12
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3552024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	20 AUG 2020 12:04
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3552024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:00
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3552024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☒

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

SUBJECT WILLING TO
CONTINUE FOLLOW UP, BUT
NOT WILLING TO HAVE
SECOND VACCINATION

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing? _____

What was the route of administration for the study treatment? _____

US3552024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	14 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:02 (24 HR)
Collection date and time (derived)	14 SEP 2020 12:02

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:44

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:05	14 SEP 2020 12:05
Nasopharyngeal Swab 2	No		

US3552024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3552024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3552024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	12 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:09 (24 HR)
Collection date and time (derived)	12 OCT 2020 10:09

US3552024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 64

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

15 OCT 2020 15:25:52

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 OCT 2020 02:11:26

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 OCT 2020 03:45:38
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 92

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

12 NOV 2020 08:55:22

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 02:28:22
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

22 NOV 2020 21:30:33

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2020 00:01

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09 DEC 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

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23 DEC 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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26 DEC 2020 00:01

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30 DEC 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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06 JAN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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13 JAN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

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20 JAN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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27 JAN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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03 FEB 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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10 FEB 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

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17 FEB 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

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24 FEB 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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03 MAR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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08 SEP 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

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19 JAN 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

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26 JAN 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

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02 FEB 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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09 FEB 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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16 FEB 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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09 MAR 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

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16 MAR 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

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06 APR 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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09 APR 2022 00:01

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13 APR 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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16 APR 2022 00:01

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20 APR 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

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27 APR 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

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15 JUN 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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06 JUL 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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09 JUL 2022 00:01

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13 JUL 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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23 JUL 2022 00:01

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27 JUL 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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30 JUL 2022 00:01

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03 AUG 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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10 AUG 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

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31 AUG 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

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07 SEP 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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10 SEP 2022 00:01

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14 SEP 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3552024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552024

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552024

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:44

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3552024

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:38:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552024

Folder: **Unscheduled 08 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: 26 Nov 2020 09:38:44

Visit Date	08 SEP 2020

Please check all assessments that apply for this visit

Physical Exam	False

Vital Signs	True

Immunogenicity Assessment	False

Pregnancy Test	False

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:30 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 08:30
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	50 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552024

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:38:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

AEID	USA-US089-2020-MRNA-1273-P30 1000001
Adverse event	NON-CARDIAC CHEST PAIN, NON-SPECIFIED
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	24 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	11 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	30 AUG 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

308 of 1557

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

STATES DEVELOPED CHEST PAIN 24AUG AFTER STARTING A GENERATOR IN HIS GARAGE. PAIN IS INTERMITTENT, COMES WITH SNEEZING OR MOVING A CERTAIN WAY. WENT TO URGENT CARE 29AUG AND SENT TO HOSPITAL WHERE HE WAS ADMITTED OVERNIGHT FOR TESTING AND OBSERVATION. HAD EKG, X-RAYS, LAB WORK, ENZYME TESTS AND STRESS TEST. SUBJECT STATES ALL TESTS WERE NEGATIVE AND HE WAS DISCHARGED AND REFERRED TO HIS PCP. STILL HAVING INTERMITTENT PAIN WITH CERTAIN MOVEMENTS.

CBC, CMP, CARDIAC ENZYMES AND TROPONINS WERE NORMAL. EKG SHOWED SINUS BRADYCARDIA. CHEST X RAY SHOWS NO ACUTE CARDIOPULMONARY DISEASE. NORMAL CARDIAC EXAM ASIDE FROM BRADYCARDIA PER HOSPITAL PHYSICIAN. STRESS TEST RESULTS NOT AVAILABLE BUT REPORTED TO BE NEGATIVE BY SUBJECT. NO SURGICAL INTERVENTIONS, NO NEW MEDICATIONS, NO ADDITIONAL TREATMENTS PER SUBJECT.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

AEID	
Adverse event	SEASONAL ALLERGIES
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	18 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	21 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

311 of 1557

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:38:44

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

Name of Medication	LOSARTAN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN JUN 2009	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

Name of Medication	AMLODIPINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	UN JUL 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

Name of Medication	TIMOLOL MALEATE 0.5%
Prophylaxis	Yes ☐ No ☒
Indication	GLAUCOMA
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	DROP
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☒ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

Name of Medication	AMLODIPINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		UN JUL 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒
	No ☐
Indication	INFLUENZA PREVENTION
Dose per administration	1
Dose unit	mg ☐
	ug ☐
	mL ☐
	g ☐
	IU ☐
	tablet ☐
	capsule ☐
	puff ☐
	Other ☒
If dose unit is Other, specify	INJECTION
Frequency	once daily ☐
	twice daily ☐
	three times daily ☐
	four times daily ☐
	every other day ☐
	every week ☐
	every month ☐
	as needed ☐
	once ☒
	unknown ☐
	other ☐
If frequency is Other, specify	
Route of administration	Oral ☐
	Topical ☐
	Subcutaneous ☐
	Transdermal ☐
	Intraocular ☐
	Intramuscular ☒

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3552024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:38:44

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3552024

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:44

Date of dosing discontinuation (dd MMM yyyy)

14 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☒

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

SUBJECT CONSENTS FOR
FOLLOW-UP, BUT NOT FOR
SECOND VACCINATION.

US3552024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:38:44

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

SAEID	USA-US089-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:38:44

SAEID	USA-US089-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/SEP/2020 13:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:38:44

SAEID	USA-US089-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/SEP/2020 12:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:38:44

SAEID	USA-US089-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	13/SEP/2020 06:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:38:44

SAEID	USA-US089-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/SEP/2020 14:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:38:44

SAEID	USA-US089-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/SEP/2020 08:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:38:44

SAEID	USA-US089-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/OCT/2020 08:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3552024 (Prod: Saint Louis University)

US3552024

Form: Participant Creation

Generated On: 26 Nov 2020 09:38:44

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3552024'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 16:59:26

US3552024

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:26:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:26:08
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:36:47

US3552024

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:26:14
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:26:08
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:59:26

US3552024

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:26:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:26:08
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:36:47

US3552024

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Aug 2020 12:36:47

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 16:59:27

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Age](#)

Audit	User	Time (GMT)
User entered '62'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '62'	System	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

White

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Black](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:44

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 16:59:26

US3552024

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:02:02

US3552024

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:38:44

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:02:02

US3552024

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:38:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:37:43

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Please consider adding to medical hx based on PCP records - hyperlipidemia (6/11/2009 and dyshidrotic foot dermatitis (if deemed relevant , start date not indicated in medical record)' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 00:49:25
Query 'Please consider adding to medical hx based on PCP records - hyperlipidemia (6/11/2009 and dyshidrotic foot dermatitis (if deemed relevant , start date not indicated in medical record)' answered with 'Added hyperlipidemia.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 17:34:49
User opened query 'Please consider adding to medical hx based on PCP records - hyperlipidemia (6/11/2009 and dyshidrotic foot dermatitis (if deemed relevant , start date not indicated in medical record)' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 13:24:49
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:39:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 12:39:21
Data point term sent to Coder	System	14 Aug 2020 12:39:08
User entered 'hypertension'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un Jun 1999'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jun 1999'	System	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1999'	System	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:57:22
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma both eyes - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 18:52:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	29 Sep 2020 18:52:12
Data point term sent to Coder	System	29 Sep 2020 18:46:28
Query 'Per DM CLR: Please specify the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	29 Sep 2020 18:46:05
Coding entries removed.	Cassandra Zehenny (b) (4)	29 Sep 2020 18:46:00
User entered 'bilateral GLAUCOMA' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	29 Sep 2020 18:46:00
User opened query 'Per DM CLR: Please specify the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:53:25
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 12:39:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	14 Aug 2020 12:39:22
Data point term sent to Coder	System	14 Aug 2020 12:39:08
User entered 'glaucoma'	Stanley Doublin (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1999'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1999'	System	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 12:41:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 12:41:17
Data point term sent to Coder	System	14 Aug 2020 12:40:11
User entered 'CATARACT right eye' reason for change: Data Entry Error	Stanley Dublin (b) (4)	14 Aug 2020 12:39:29
User entered 'cataract'	Stanley Dublin (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un Dec 2017'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Dec 2017'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Intraocular lens implant, LLT: Lens implant - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 11:54:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 11:54:27
User closed query 'Per DM CLR: Please provide separate entry for these two events. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:49:17
Query 'Per DM CLR: Please provide separate entry for these two events. Update as appropriate.' answered with 'updated per query request' (Site from DM).	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:06
Data point term sent to Coder	System	02 Oct 2020 18:22:01
User entered 'CATARACT LENS IMPLANT IN RIGHT EYE' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:00
User opened query 'Per DM CLR: Please provide separate entry for these two events. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 13:10:10
User closed query 'Per DM CLR: Please specify the laterality of LASER SURGERY AND CATARACT LENS IMPLANT (e.g. Right, Left, or Bilateral Eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:57:35
Data point term sent to Coder	System	29 Sep 2020 18:47:30
Query 'Per DM CLR: Please specify the laterality of LASER SURGERY AND CATARACT LENS IMPLANT (e.g. Right, Left, or Bilateral Eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM). Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 18:46:55
User entered 'LASER SURGERY AND CATARACT LENS IMPLANT in right eye' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 18:46:50

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the laterality of LASER SURGERY AND CATARACT LENS IMPLANT (e.g. Right, Left, or Bilateral Eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:54:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Intraocular lens implant, LLT: Lens implant - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 11:11:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 11:11:18
Data point term sent to Coder	System	14 Aug 2020 12:42:14
User entered 'LASER SURGERY AND CATARACT LENS IMPLANT'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un Dec 2017'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un Dec 2017'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR, Please confirm if subject is taking concomitant medication for this condition and ensure data is entered in Concomitant Medication page if applicable. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:21:55
Query 'Per ETRTR, Please confirm if subject is taking concomitant medication for this condition and ensure data is entered in Concomitant Medication page if applicable. ' answered with 'Diet controlled' (Site from CRA).	Cassandra Zehenny (b) (4)	04 Nov 2020 16:37:03
User opened query 'Per ETRTR, Please confirm if subject is taking concomitant medication for this condition and ensure data is entered in Concomitant Medication page if applicable. ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 22:33:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 17:24:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 17:24:02
Data point term sent to Coder	System	30 Sep 2020 17:22:57
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Jun 2009'	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jun 2009'	System	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2009'	System	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Eye laser surgery, LLT: Eye laser surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 13:56:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 13:56:52
Data point term sent to Coder	System	02 Oct 2020 18:23:02
User entered 'R eye laser surgery for cataract'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un Dec 2017'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Dec 2017'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:00'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:00'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '71' in	Stanley Dublin (b) (4)	14 Aug 2020 12:42:47
DataPoint set to visible.	(b) (4) System	13 Aug 2020 17:02:02

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '191.4' lb	Stanley Dublin (b) (4)	14 Aug 2020 12:42:47
DataPoint set to visible.	(b) (4) System	13 Aug 2020 17:02:02

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '26.75070'	System	16 Sep 2020 23:55:34
User entered '26.8'	System	14 Aug 2020 12:42:47
DataPoint set to visible.	System	13 Aug 2020 17:02:02

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Aug 2020 12:42:47
DataPoint set to visible.	System	13 Aug 2020 17:02:02

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 11:40:43
Query 'Data is required. Please provide.' answered with 'nd' (Site from System).	Stanley Doublin (b) (4)	14 Aug 2020 12:42:52
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 12:42:47
User entered empty.	Stanley Doublin (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:05

US3552024

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 04:58:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 18:45:48
User entered '13 Aug 2020'	Stanley Dublin (b) (4)	14 Aug 2020 12:43:05
	(b) (4)	

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

Other

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:44

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:56

US3552024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:56

US3552024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:56

US3552024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	14 Aug 2020 12:43:56

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 16:59:33

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:13:36
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:13:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:59:33
User entered '103592' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 16:59:33

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 16:59:33

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:45:05

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:45:05

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:45:05

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:45:05

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:45:05

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4)	21 Sep 2020 16:58:18
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:19:53
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:03:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:44

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:44

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:44

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:44

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Dublin (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:00'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:00'	System	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '52'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '85'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:44

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:44

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:13:33
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'data is correct' (Site from System).	Stanley Dublin (b) (4)	14 Aug 2020 12:58:56
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	14 Aug 2020 12:46:53
User entered '13:06'	Stanley Dublin (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 13:06'	System	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '54'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '135'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 19:05:06

US3552024

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 19:05:06

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:36'	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:36'	System	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:47:19

US3552024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:47:19

US3552024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:45'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:47:19

US3552024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:45'	System	14 Aug 2020 12:47:19

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:44

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:47:42

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	14 Aug 2020 12:47:42

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:47:42

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '11:49'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:47:42

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:49'	System	14 Aug 2020 12:47:42

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	14 Aug 2020 12:47:47

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:47:47

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:47:47

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 12:47:47

US3552024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	20 Aug 2020 19:29:16

US3552024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:29:16

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:10:30', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '49516ec0-3b86-4d21-9d19-c2e1c2d40d7a'	System	13 Aug 2020 18:10:52
User entered 'Yes (Y)'	System	13 Aug 2020 18:10:52

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:10:37', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '49516ec0-3b86-4d21-9d19-c2e1c2d40d7a' User entered '98.1'	System	13 Aug 2020 18:10:52
	System	13 Aug 2020 18:10:52

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:10:43', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '49516ec0-3b86-4d21-9d19-c2e1c2d40d7a'	System	13 Aug 2020 18:10:52
User entered 'No (N)'	System	13 Aug 2020 18:10:52

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:10:51', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '49516ec0-3b86-4d21-9d19-c2e1c2d40d7a'	System	13 Aug 2020 18:10:52
User entered '13 Aug 2020 13:10'	System	13 Aug 2020 18:10:52

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:56'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:26'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:23:57', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '1ba7622f-d0ca-4762-8aa8-367dd13f080e'	System	13 Aug 2020 21:24:24
User entered 'Yes (Y)'	System	13 Aug 2020 21:24:24

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:24:07', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '1ba7622f-d0ca-4762-8aa8-367dd13f080e'	System	13 Aug 2020 21:24:24
User entered '98.2'	System	13 Aug 2020 21:24:24

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:24:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '1ba7622f-d0ca-4762-8aa8-367dd13f080e'	System	13 Aug 2020 21:24:24
User entered 'No (N)'	System	13 Aug 2020 21:24:24

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:24:21', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '1ba7622f-d0ca-4762-8aa8-367dd13f080e'	System	13 Aug 2020 21:24:24
User entered '13 Aug 2020 16:24'	System	13 Aug 2020 21:24:24

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:21'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 2'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T12:59:14', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'db99796f-34e2-411f-b091-6510264884cf'	System	14 Aug 2020 18:01:37
User entered 'Yes (Y)'	System	14 Aug 2020 18:01:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:00:58', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'db99796f-34e2-411f-b091-6510264884cf'	System	14 Aug 2020 18:01:37
User entered '97.1'	System	14 Aug 2020 18:01:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:01:24', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'db99796f-34e2-411f-b091-6510264884cf'	System	14 Aug 2020 18:01:37
User entered 'No (N)'	System	14 Aug 2020 18:01:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:01:35', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'db99796f-34e2-411f-b091-6510264884cf'	System	14 Aug 2020 18:01:37
User entered '14 Aug 2020 13:01'	System	14 Aug 2020 18:01:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 3'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:03:45', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '79a7a5d0-f524-427e-8ba9-f454d8a5348d' User entered 'Yes (Y)'	System	15 Aug 2020 17:06:04

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:05:32', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '79a7a5d0-f524-427e-8ba9-f454d8a5348d' User entered '97.7'	System	15 Aug 2020 17:06:04

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:05:50', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '79a7a5d0-f524-427e-8ba9-f454d8a5348d'	System	15 Aug 2020 17:06:04
User entered 'No (N)'	System	15 Aug 2020 17:06:04

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:06:02', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '79a7a5d0-f524-427e-8ba9-f454d8a5348d' User entered '15 Aug 2020 12:06'	System	15 Aug 2020 17:06:04
	System	15 Aug 2020 17:06:04

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 4'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:20:35', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '37a311e8-4a00-48ed-a385-9f71dd798908'	System	16 Aug 2020 17:22:01
User entered 'Yes (Y)'	System	16 Aug 2020 17:22:01

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:21:35', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '37a311e8-4a00-48ed-a385-9f71dd798908'	System	16 Aug 2020 17:22:01
User entered '97.0'	System	16 Aug 2020 17:22:01

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:21:53', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '37a311e8-4a00-48ed-a385-9f71dd798908'	System	16 Aug 2020 17:22:01
User entered 'No (N)'	System	16 Aug 2020 17:22:01

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:21:59', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '37a311e8-4a00-48ed-a385-9f71dd798908'	System	16 Aug 2020 17:22:01
User entered '16 Aug 2020 12:21'	System	16 Aug 2020 17:22:01

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 5'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:03:50', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '6a3fe053-4e77-4514-844a-9a219562a1d0'	System	17 Aug 2020 17:04:37
User entered 'Yes (Y)'	System	17 Aug 2020 17:04:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:04:22', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '6a3fe053-4e77-4514-844a-9a219562a1d0'	System	17 Aug 2020 17:04:37
User entered '96.8'	System	17 Aug 2020 17:04:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:04:28', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '6a3fe053-4e77-4514-844a-9a219562a1d0'	System	17 Aug 2020 17:04:37
User entered 'No (N)'	System	17 Aug 2020 17:04:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:04:32', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '6a3fe053-4e77-4514-844a-9a219562a1d0'	System	17 Aug 2020 17:04:37
User entered '17 Aug 2020 12:04'	System	17 Aug 2020 17:04:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 6'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:09:10', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '42129f72-f74a-4735-8a95-1a1fb6970f8f'	System	18 Aug 2020 17:11:03
User entered 'Yes (Y)'	System	18 Aug 2020 17:11:03

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:10:23', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '42129f72-f74a-4735-8a95-1a1fb6970f8f'	System	18 Aug 2020 17:11:03
User entered '96.8'	System	18 Aug 2020 17:11:03

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:10:55', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '42129f72-f74a-4735-8a95-1a1fb6970f8f'	System	18 Aug 2020 17:11:03
User entered 'No (N)'	System	18 Aug 2020 17:11:03

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '42129f72-f74a-4735-8a95-1a1fb6970f8f'	System	18 Aug 2020 17:11:03
User entered '18 Aug 2020 12:11'	System	18 Aug 2020 17:11:03

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 7'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:09:01', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '817436ac-789b-4d2d-8aaf-ee4a16b92402'	System	19 Aug 2020 17:11:49
User entered 'Yes (Y)'	System	19 Aug 2020 17:11:49

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:11:19', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '817436ac-789b-4d2d-8aaf-ee4a16b92402'	System	19 Aug 2020 17:11:49
User entered '97.0'	System	19 Aug 2020 17:11:49

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:11:26', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '817436ac-789b-4d2d-8aaf-ee4a16b92402'	System	19 Aug 2020 17:11:49
User entered 'No (N)'	System	19 Aug 2020 17:11:49

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:11:46', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '817436ac-789b-4d2d-8aaf-ee4a16b92402'	System	19 Aug 2020 17:11:49
User entered '19 Aug 2020 12:11'	System	19 Aug 2020 17:11:49

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:11:08', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b4b53055-b054-4c72-86e9-7e47c603bbbe'	System	13 Aug 2020 18:11:44
User entered 'None (1)'	System	13 Aug 2020 18:11:44

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:11:22', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b4b53055-b054-4c72-86e9-7e47c603bbbe'	System	13 Aug 2020 18:11:44
User entered 'No (N)'	System	13 Aug 2020 18:11:44

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:11:28', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b4b53055-b054-4c72-86e9-7e47c603bbbe'	System	13 Aug 2020 18:11:44
User entered 'No (N)'	System	13 Aug 2020 18:11:44

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:11:37', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b4b53055-b054-4c72-86e9-7e47c603bbbe'	System	13 Aug 2020 18:11:44
User entered 'None (1)'	System	13 Aug 2020 18:11:44

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:11:43', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b4b53055-b054-4c72-86e9-7e47c603bbbe' User entered '13 Aug 2020 13:11'	System	13 Aug 2020 18:11:44
	System	13 Aug 2020 18:11:44

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:56'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:26'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:25:16', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '361088be-0d4d-45ff-a22d-364499527134'	System	13 Aug 2020 21:26:33
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 21:26:33

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:25:59', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '361088be-0d4d-45ff-a22d-364499527134'	System	13 Aug 2020 21:26:33
User entered 'No (N)'	System	13 Aug 2020 21:26:33

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:26:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '361088be-0d4d-45ff-a22d-364499527134'	System	13 Aug 2020 21:26:33
User entered 'No (N)'	System	13 Aug 2020 21:26:33

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:26:21', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '361088be-0d4d-45ff-a22d-364499527134'	System	13 Aug 2020 21:26:33
User entered 'None (1)'	System	13 Aug 2020 21:26:33

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:26:30', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '361088be-0d4d-45ff-a22d-364499527134'	System	13 Aug 2020 21:26:33
User entered '13 Aug 2020 16:26'	System	13 Aug 2020 21:26:33

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:21'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 2'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:02:09', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3485fbec-e485-4a93-81d5-0539e0fc1725'	System	14 Aug 2020 18:02:36
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 18:02:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:02:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3485fbec-e485-4a93-81d5-0539e0fc1725'	System	14 Aug 2020 18:02:36
User entered 'No (N)'	System	14 Aug 2020 18:02:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:02:18', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3485fbec-e485-4a93-81d5-0539e0fc1725'	System	14 Aug 2020 18:02:36
User entered 'No (N)'	System	14 Aug 2020 18:02:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:02:26', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3485fbec-e485-4a93-81d5-0539e0fc1725'	System	14 Aug 2020 18:02:36
User entered 'None (1)'	System	14 Aug 2020 18:02:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:02:34', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3485fbec-e485-4a93-81d5-0539e0fc1725'	System	14 Aug 2020 18:02:36
User entered '14 Aug 2020 13:02'	System	14 Aug 2020 18:02:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 3'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:06:27', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '4fcf88c5-6e42-4315-9af0-36c229a6574e'	System	15 Aug 2020 17:07:00
User entered 'None (1)'	System	15 Aug 2020 17:07:00

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:06:31', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '4fcf88c5-6e42-4315-9af0-36c229a6574e'	System	15 Aug 2020 17:07:00
User entered 'No (N)'	System	15 Aug 2020 17:07:00

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:06:42', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '4fcf88c5-6e42-4315-9af0-36c229a6574e'	System	15 Aug 2020 17:07:00
User entered 'No (N)'	System	15 Aug 2020 17:07:00

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:44

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:06:49', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '4fcf88c5-6e42-4315-9af0-36c229a6574e'	System	15 Aug 2020 17:07:00
User entered 'None (1)'	System	15 Aug 2020 17:07:00

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:06:57', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '4fcf88c5-6e42-4315-9af0-36c229a6574e'	System	15 Aug 2020 17:07:00
User entered '15 Aug 2020 12:06'	System	15 Aug 2020 17:07:00

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 4'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:15', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c1fea472-1c19-44c8-bb29-c86f158edd26'	System	16 Aug 2020 17:22:36
User entered 'None (1)'	System	16 Aug 2020 17:22:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:19', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c1fea472-1c19-44c8-bb29-c86f158edd26'	System	16 Aug 2020 17:22:36
User entered 'No (N)'	System	16 Aug 2020 17:22:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:23', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c1fea472-1c19-44c8-bb29-c86f158edd26'	System	16 Aug 2020 17:22:36
User entered 'No (N)'	System	16 Aug 2020 17:22:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:44

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:29', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c1fea472-1c19-44c8-bb29-c86f158edd26'	System	16 Aug 2020 17:22:36
User entered 'None (1)'	System	16 Aug 2020 17:22:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:34', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c1fea472-1c19-44c8-bb29-c86f158edd26'	System	16 Aug 2020 17:22:36
User entered '16 Aug 2020 12:22'	System	16 Aug 2020 17:22:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 5'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:04:43', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cac3df19-da11-4cc4-b93f-3e23a2bdfa81'	System	17 Aug 2020 17:05:06
User entered 'None (1)'	System	17 Aug 2020 17:05:06

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:04:47', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cac3df19-da11-4cc4-b93f-3e23a2bdfa81'	System	17 Aug 2020 17:05:06
User entered 'No (N)'	System	17 Aug 2020 17:05:06

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:04:51', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cac3df19-da11-4cc4-b93f-3e23a2bdfa81'	System	17 Aug 2020 17:05:06
User entered 'No (N)'	System	17 Aug 2020 17:05:06

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:04:58', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cac3df19-da11-4cc4-b93f-3e23a2bdfa81'	System	17 Aug 2020 17:05:06
User entered 'None (1)'	System	17 Aug 2020 17:05:06

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:05:03', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cac3df19-da11-4cc4-b93f-3e23a2bdfa81'	System	17 Aug 2020 17:05:06
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 17:05:06

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 6'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:16', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b215bf36-8590-43a5-9937-6d5bb52b1baf'	System	18 Aug 2020 17:11:42
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 17:11:42

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:20', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b215bf36-8590-43a5-9937-6d5bb52b1baf'	System	18 Aug 2020 17:11:42
User entered 'No (N)'	System	18 Aug 2020 17:11:42

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:24', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b215bf36-8590-43a5-9937-6d5bb52b1baf'	System	18 Aug 2020 17:11:42
User entered 'No (N)'	System	18 Aug 2020 17:11:42

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:30', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b215bf36-8590-43a5-9937-6d5bb52b1baf'	System	18 Aug 2020 17:11:42
User entered 'None (1)'	System	18 Aug 2020 17:11:42

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:38', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'b215bf36-8590-43a5-9937-6d5bb52b1baf'	System	18 Aug 2020 17:11:42
User entered '18 Aug 2020 12:11'	System	18 Aug 2020 17:11:42

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 7'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:44

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:11:54', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a510bf47-1d9d-4dc1-8744-938869ade837'	System	19 Aug 2020 17:12:14
User entered 'None (1)'	System	19 Aug 2020 17:12:14

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:11:58', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a510bf47-1d9d-4dc1-8744-938869ade837'	System	19 Aug 2020 17:12:14
User entered 'No (N)'	System	19 Aug 2020 17:12:14

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:02', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a510bf47-1d9d-4dc1-8744-938869ade837'	System	19 Aug 2020 17:12:14
User entered 'No (N)'	System	19 Aug 2020 17:12:14

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:44

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:05', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a510bf47-1d9d-4dc1-8744-938869ade837'	System	19 Aug 2020 17:12:14
User entered 'None (1)'	System	19 Aug 2020 17:12:14

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:10', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a510bf47-1d9d-4dc1-8744-938869ade837'	System	19 Aug 2020 17:12:14
User entered '19 Aug 2020 12:12'	System	19 Aug 2020 17:12:14

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:11:54', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a03f1b8b-e67e-48a6-b943-03c56eff487d'	System	13 Aug 2020 18:12:46
User entered 'None (0)'	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:11:59', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a03f1b8b-e67e-48a6-b943-03c56eff487d'	System	13 Aug 2020 18:12:46
User entered 'None (0)'	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:12:05', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a03f1b8b-e67e-48a6-b943-03c56eff487d'	System	13 Aug 2020 18:12:46
User entered 'None (0)'	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:12:15', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a03f1b8b-e67e-48a6-b943-03c56eff487d'	System	13 Aug 2020 18:12:46
User entered 'None (0)'	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:12:19', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a03f1b8b-e67e-48a6-b943-03c56eff487d'	System	13 Aug 2020 18:12:46
User entered 'None (0)'	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:12:22', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a03f1b8b-e67e-48a6-b943-03c56eff487d'	System	13 Aug 2020 18:12:46
User entered 'None (0)'	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:12:32', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a03f1b8b-e67e-48a6-b943-03c56eff487d'	System	13 Aug 2020 18:12:46
User entered 'No (N)'	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T13:12:41', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a03f1b8b-e67e-48a6-b943-03c56eff487d'	System	13 Aug 2020 18:12:46
User entered '13 Aug 2020 13:12'	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:56'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:26'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:26:53', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3a748d0b-cf12-4966-a005-d481a873e272'	System	13 Aug 2020 21:27:41
User entered 'None (0)'	System	13 Aug 2020 21:27:41

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:26:59', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3a748d0b-cf12-4966-a005-d481a873e272'	System	13 Aug 2020 21:27:41
User entered 'None (0)'	System	13 Aug 2020 21:27:41

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:27:07', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3a748d0b-cf12-4966-a005-d481a873e272'	System	13 Aug 2020 21:27:41
User entered 'None (0)'	System	13 Aug 2020 21:27:41

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:27:12', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3a748d0b-cf12-4966-a005-d481a873e272'	System	13 Aug 2020 21:27:41
User entered 'None (0)'	System	13 Aug 2020 21:27:41

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:27:16', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3a748d0b-cf12-4966-a005-d481a873e272'	System	13 Aug 2020 21:27:41
User entered 'None (0)'	System	13 Aug 2020 21:27:41

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:27:20', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3a748d0b-cf12-4966-a005-d481a873e272'	System	13 Aug 2020 21:27:41
User entered 'None (0)'	System	13 Aug 2020 21:27:41

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:27:29', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3a748d0b-cf12-4966-a005-d481a873e272'	System	13 Aug 2020 21:27:41
User entered 'No (N)'	System	13 Aug 2020 21:27:41

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-13T16:27:40', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3a748d0b-cf12-4966-a005-d481a873e272'	System	13 Aug 2020 21:27:41
User entered '13 Aug 2020 16:27'	System	13 Aug 2020 21:27:41

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:21'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 2'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:02:42', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '0011355f-c3fa-4fcd-9ea2-758ecf0b34ee'	System	14 Aug 2020 18:03:25
User entered 'No interference with activity (1)'	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:02:47', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '0011355f-c3fa-4fcd-9ea2-758ecf0b34ee'	System	14 Aug 2020 18:03:25
User entered 'None (0)'	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:02:53', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '0011355f-c3fa-4fcd-9ea2-758ecf0b34ee'	System	14 Aug 2020 18:03:25
User entered 'None (0)'	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:03:01', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '0011355f-c3fa-4fcd-9ea2-758ecf0b34ee'	System	14 Aug 2020 18:03:25
User entered 'None (0)'	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:03:04', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '0011355f-c3fa-4fcd-9ea2-758ecf0b34ee'	System	14 Aug 2020 18:03:25
User entered 'None (0)'	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:03:08', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '0011355f-c3fa-4fcd-9ea2-758ecf0b34ee'	System	14 Aug 2020 18:03:25
User entered 'None (0)'	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:03:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '0011355f-c3fa-4fcd-9ea2-758ecf0b34ee'	System	14 Aug 2020 18:03:25
User entered 'No (N)'	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-14T13:03:22', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '0011355f-c3fa-4fcd-9ea2-758ecf0b34ee'	System	14 Aug 2020 18:03:25
User entered '14 Aug 2020 13:03'	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 3'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:07:08', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '742196ff-d0c5-4800-acfe-c75b42a4a871'	System	15 Aug 2020 17:07:50
User entered 'No interference with activity (1)'	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:07:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '742196ff-d0c5-4800-acfe-c75b42a4a871'	System	15 Aug 2020 17:07:50
User entered 'None (0)'	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:07:19', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '742196ff-d0c5-4800-acfe-c75b42a4a871'	System	15 Aug 2020 17:07:50
User entered 'None (0)'	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:07:23', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '742196ff-d0c5-4800-acfe-c75b42a4a871'	System	15 Aug 2020 17:07:50
User entered 'None (0)'	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:07:26', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '742196ff-d0c5-4800-acfe-c75b42a4a871'	System	15 Aug 2020 17:07:50
User entered 'None (0)'	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:07:29', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '742196ff-d0c5-4800-acfe-c75b42a4a871'	System	15 Aug 2020 17:07:50
User entered 'None (0)'	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:07:38', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '742196ff-d0c5-4800-acfe-c75b42a4a871'	System	15 Aug 2020 17:07:50
User entered 'No (N)'	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-15T12:07:46', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '742196ff-d0c5-4800-acfe-c75b42a4a871'	System	15 Aug 2020 17:07:50
User entered '15 Aug 2020 12:07'	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 4'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:42', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'd3d9a5c1-2469-40c1-96c5-481a1dc3ff23'	System	16 Aug 2020 17:23:14
User entered 'None (0)'	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:45', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'd3d9a5c1-2469-40c1-96c5-481a1dc3ff23'	System	16 Aug 2020 17:23:14
User entered 'None (0)'	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:49', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'd3d9a5c1-2469-40c1-96c5-481a1dc3ff23'	System	16 Aug 2020 17:23:14
User entered 'None (0)'	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:52', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'd3d9a5c1-2469-40c1-96c5-481a1dc3ff23'	System	16 Aug 2020 17:23:14
User entered 'None (0)'	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:55', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'd3d9a5c1-2469-40c1-96c5-481a1dc3ff23'	System	16 Aug 2020 17:23:14
User entered 'None (0)'	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:22:58', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'd3d9a5c1-2469-40c1-96c5-481a1dc3ff23'	System	16 Aug 2020 17:23:14
User entered 'None (0)'	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:23:02', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'd3d9a5c1-2469-40c1-96c5-481a1dc3ff23'	System	16 Aug 2020 17:23:14
User entered 'No (N)'	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-16T12:23:10', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'd3d9a5c1-2469-40c1-96c5-481a1dc3ff23'	System	16 Aug 2020 17:23:14
User entered '16 Aug 2020 12:23'	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 5'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:05:09', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'eed59244-af56-45e5-961d-ddb8d1e14734'	System	17 Aug 2020 17:05:37
User entered 'None (0)'	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:05:12', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'eed59244-af56-45e5-961d-ddb8d1e14734'	System	17 Aug 2020 17:05:37
User entered 'None (0)'	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:05:15', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'eed59244-af56-45e5-961d-ddb8d1e14734'	System	17 Aug 2020 17:05:37
User entered 'None (0)'	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:05:19', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'eed59244-af56-45e5-961d-ddb8d1e14734'	System	17 Aug 2020 17:05:37
User entered 'None (0)'	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:05:22', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'eed59244-af56-45e5-961d-ddb8d1e14734'	System	17 Aug 2020 17:05:37
User entered 'None (0)'	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:05:24', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'eed59244-af56-45e5-961d-ddb8d1e14734'	System	17 Aug 2020 17:05:37
User entered 'None (0)'	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:05:28', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'eed59244-af56-45e5-961d-ddb8d1e14734'	System	17 Aug 2020 17:05:37
User entered 'No (N)'	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-17T12:05:34', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'eed59244-af56-45e5-961d-ddb8d1e14734'	System	17 Aug 2020 17:05:37
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 6'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:44', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a2d93923-229d-45d4-a65a-b54f63b10c8e'	System	18 Aug 2020 17:12:15
User entered 'None (0)'	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:48', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a2d93923-229d-45d4-a65a-b54f63b10c8e'	System	18 Aug 2020 17:12:15
User entered 'None (0)'	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:52', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a2d93923-229d-45d4-a65a-b54f63b10c8e'	System	18 Aug 2020 17:12:15
User entered 'None (0)'	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:57', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a2d93923-229d-45d4-a65a-b54f63b10c8e'	System	18 Aug 2020 17:12:15
User entered 'None (0)'	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:11:59', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a2d93923-229d-45d4-a65a-b54f63b10c8e'	System	18 Aug 2020 17:12:15
User entered 'None (0)'	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:12:02', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a2d93923-229d-45d4-a65a-b54f63b10c8e'	System	18 Aug 2020 17:12:15
User entered 'None (0)'	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:12:06', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a2d93923-229d-45d4-a65a-b54f63b10c8e'	System	18 Aug 2020 17:12:15
User entered 'No (N)'	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-18T12:12:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a2d93923-229d-45d4-a65a-b54f63b10c8e'	System	18 Aug 2020 17:12:15
User entered '18 Aug 2020 12:12'	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 7'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:20', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '757a7c5e-321f-49e3-882e-55d70b185d70'	System	19 Aug 2020 17:12:50
User entered 'None (0)'	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:23', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '757a7c5e-321f-49e3-882e-55d70b185d70'	System	19 Aug 2020 17:12:50
User entered 'None (0)'	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:26', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '757a7c5e-321f-49e3-882e-55d70b185d70'	System	19 Aug 2020 17:12:50
User entered 'None (0)'	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:32', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '757a7c5e-321f-49e3-882e-55d70b185d70'	System	19 Aug 2020 17:12:50
User entered 'None (0)'	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:35', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '757a7c5e-321f-49e3-882e-55d70b185d70'	System	19 Aug 2020 17:12:50
User entered 'None (0)'	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:38', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '757a7c5e-321f-49e3-882e-55d70b185d70'	System	19 Aug 2020 17:12:50
User entered 'None (0)'	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:44', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '757a7c5e-321f-49e3-882e-55d70b185d70'	System	19 Aug 2020 17:12:50
User entered 'No (N)'	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-19T12:12:48', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '757a7c5e-321f-49e3-882e-55d70b185d70'	System	19 Aug 2020 17:12:50
User entered '19 Aug 2020 12:12'	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 17:11:42
User entered 'Day 8'	System	18 Aug 2020 17:11:42

US3552024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-20T12:04:23', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '9ca354cc-9fb6-41a3-bfeb-b39749b64635'	System	20 Aug 2020 17:04:32
User entered 'No (N)'	System	20 Aug 2020 17:04:32

US3552024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-08-20T12:04:30', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '9ca354cc-9fb6-41a3-bfeb-b39749b64635'	System	20 Aug 2020 17:04:32
User entered '20 Aug 2020 12:04'	System	20 Aug 2020 17:04:32

US3552024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:11:42

US3552024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:11:42

US3552024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	20 Aug 2020 19:29:39

US3552024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Aug 2020 16:33:24
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	27 Aug 2020 16:33:24
User entered '20 Aug 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	27 Aug 2020 16:33:24
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Aug 2020 16:32:59
User entered '27 Aug 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	27 Aug 2020 16:32:59
User entered '20 Aug 2020'	Joan Siegner (b) (4)	20 Aug 2020 19:29:39

US3552024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4)	20 Aug 2020 19:29:39

US3552024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	20 Aug 2020 19:29:39

US3552024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:58:53

US3552024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:58:53

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:59:06

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:59:06

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	27 Aug 2020 15:59:06

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:59:06

US3552024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Sep 2020 16:40:35

US3552024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:40:35

US3552024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Sep 2020 16:41:08

US3552024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	09 Nov 2020 15:51:02
User entered '3 Sep 2020'	Joan Siegner (b) (4)	03 Sep 2020 16:41:08

US3552024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4)	03 Sep 2020 16:41:08

US3552024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	03 Sep 2020 16:41:08

US3552024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	14 Sep 2020 18:44:55

US3552024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 18:44:55

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	14 Sep 2020 18:45:48

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Joan Siegner (b) (4)	14 Sep 2020 18:45:48

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Joan Siegner (b) (4)	14 Sep 2020 18:45:48

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	14 Sep 2020 18:45:48

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:00'	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '55'	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:38

US3552024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:38

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joan Siegner (b) (4)	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

If No, reason not given

Audit	User	Time (GMT)
User closed query 'If there is " Other" option in dropdown, please use that and comment that Subject remain on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 20:12:31
Query 'If there is " Other" option in dropdown, please use that and comment that Subject remain on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you' answered with 'Updated per query request' (Site from CRA).	Heather Douds (b) (4) (b) (4)	24 Sep 2020 13:27:07
User entered 'Other (OTHER)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	24 Sep 2020 13:26:58
User opened query 'If there is " Other" option in dropdown, please use that and comment that Subject remain on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 15:44:55
Query 'If there is option to use " Other" and comment that Subject remain on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you!' canceled (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 15:44:09
User opened query 'If there is option to use " Other" and comment that Subject remain on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you!' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 15:37:15
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)'	Joan Siegner (b) (4)	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered 'subject willing to continue follow up, but not willing to have second vaccination'	Joan Siegner (b) (4) [REDACTED] [REDACTED]	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	14 Sep 2020 18:47:33

US3552024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Joan Siegner (b) (4)	14 Sep 2020 18:47:33

US3552024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:02'	Joan Siegner (b) (4)	14 Sep 2020 18:47:33

US3552024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:02'	System	14 Sep 2020 18:47:33

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Joan Siegner (b) (4)	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Joan Siegner (b) (4)	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '12:05'	Joan Siegner (b) (4)	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:05'	System	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Joan Siegner (b) (4)	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joan Siegner (b) (4)	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:46

US3552024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 12:40:46

US3552024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:55

US3552024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:55

US3552024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	22 Sep 2020 12:40:55

US3552024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 12:40:55

US3552024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:48:54

US3552024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:48:54

US3552024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:49:06

US3552024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:49:06

US3552024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	28 Sep 2020 16:49:06

US3552024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:49:06

US3552024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	06 Oct 2020 12:58:17

US3552024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 12:58:17

US3552024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	06 Oct 2020 12:58:26

US3552024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	09 Nov 2020 15:51:30
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	06 Oct 2020 12:58:26

US3552024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	06 Oct 2020 12:58:26

US3552024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	06 Oct 2020 12:58:26

US3552024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	12 Oct 2020 16:33:50

US3552024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 16:33:50

US3552024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	12 Oct 2020 16:34:01

US3552024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Joan Siegner (b) (4)	12 Oct 2020 16:34:01

US3552024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Joan Siegner (b) (4)	12 Oct 2020 16:34:01

US3552024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Oct 2020 16:34:01

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joan Siegner (b) (4)	12 Oct 2020 16:34:19

US3552024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 16:34:19

US3552024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	12 Oct 2020 16:34:31

US3552024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Joan Siegner (b) (4)	12 Oct 2020 16:34:31

US3552024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:09'	Joan Siegner (b) (4)	12 Oct 2020 16:34:31

US3552024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 10:09'	System	12 Oct 2020 16:34:31

US3552024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 13:18:44

US3552024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 13:18:44

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 64'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-10-15T15:25:37', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'f335f8c9-5a09-44b1-a4b9-0f7ae1b7aa42'	System	15 Oct 2020 20:25:55
User entered 'No (N)'	System	15 Oct 2020 20:25:55

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-10-15T15:25:42', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'f335f8c9-5a09-44b1-a4b9-0f7ae1b7aa42'	System	15 Oct 2020 20:25:55
User entered 'No (N)'	System	15 Oct 2020 20:25:55

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-10-15T15:25:52', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'f335f8c9-5a09-44b1-a4b9-0f7ae1b7aa42' User entered '15 Oct 2020 15:25:52'	System	15 Oct 2020 20:25:55
	System	15 Oct 2020 20:25:55

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 71'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-10-20T02:10:50', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '76918b61-20d6-4b78-a6a0-b9ceb0889740'	System	20 Oct 2020 07:11:31
User entered 'No (N)'	System	20 Oct 2020 07:11:31

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-10-20T02:10:56', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '76918b61-20d6-4b78-a6a0-b9ceb0889740'	System	20 Oct 2020 07:11:31
User entered 'No (N)'	System	20 Oct 2020 07:11:31

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-10-20T02:11:26', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '76918b61-20d6-4b78-a6a0-b9ceb0889740'	System	20 Oct 2020 07:11:31
User entered '20 Oct 2020 02:11:26'	System	20 Oct 2020 07:11:31

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 78'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-10-27T03:45:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '26e09956-ef01-4be7-84b1-4a7ffa0445a9'	System	27 Oct 2020 08:45:40
User entered 'No (N)'	System	27 Oct 2020 08:45:40

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-10-27T03:45:23', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '26e09956-ef01-4be7-84b1-4a7ffa0445a9'	System	27 Oct 2020 08:45:40
User entered 'No (N)'	System	27 Oct 2020 08:45:40

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-10-27T03:45:38', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '26e09956-ef01-4be7-84b1-4a7ffa0445a9' User entered '27 Oct 2020 03:45:38'	System	27 Oct 2020 08:45:40
	System	27 Oct 2020 08:45:40

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 92'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-12T08:55:07', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '2be4e414-1b28-4446-92c7-f161d654d111'	System	12 Nov 2020 14:55:44
User entered 'No (N)'	System	12 Nov 2020 14:55:44

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-12T08:55:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '2be4e414-1b28-4446-92c7-f161d654d111'	System	12 Nov 2020 14:55:44
User entered 'No (N)'	System	12 Nov 2020 14:55:44

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-12T08:55:22', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '2be4e414-1b28-4446-92c7-f161d654d111'	System	12 Nov 2020 14:55:44
User entered '12 Nov 2020 08:55:22'	System	12 Nov 2020 14:55:44

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered 'Day 99'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-17T02:28:08', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c87e6798-dd27-406a-aa67-272430a078ab'	System	17 Nov 2020 08:28:24
User entered 'No (N)'	System	17 Nov 2020 08:28:24

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-17T02:28:15', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c87e6798-dd27-406a-aa67-272430a078ab'	System	17 Nov 2020 08:28:24
User entered 'No (N)'	System	17 Nov 2020 08:28:24

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-17T02:28:22', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c87e6798-dd27-406a-aa67-272430a078ab' User entered '17 Nov 2020 02:28:22'	System	17 Nov 2020 08:28:24
	System	17 Nov 2020 08:28:24

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 17:48:56

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:48:56
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 17:48:56

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '10 Oct 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '14 Oct 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-22T21:30:25', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '9c8d6f5d-9589-4a38-81c2-9408288fbc28'	System	23 Nov 2020 03:30:36
User entered 'No (N)'	System	23 Nov 2020 03:30:36

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-22T21:30:30', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '9c8d6f5d-9589-4a38-81c2-9408288fbc28'	System	23 Nov 2020 03:30:36
User entered 'No (N)'	System	23 Nov 2020 03:30:36

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-22T21:30:33', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '9c8d6f5d-9589-4a38-81c2-9408288fbc28' User entered '22 Nov 2020 21:30:33'	System	23 Nov 2020 03:30:36
	System	23 Nov 2020 03:30:36

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:18:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:18:17
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:18:17

US3552024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 13:18:56

US3552024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 13:18:56

US3552024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	10 Nov 2020 13:18:56

US3552024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 13:18:56

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:38:44

[Visit Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:24
User closed query 'Per ETRTR, please provide rationale for Unscheduled visit being performed. If related to an AE please ensure Adverse Events page is updated accordingly. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:22:34
User entered '08 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	09 Nov 2020 15:51:49
Query 'Per ETRTR, please provide rationale for Unscheduled visit being performed. If related to an AE please ensure Adverse Events page is updated accordingly. ' answered with 'related AE captured' (Site from CRA).	Cassandra Zehenny (b) (4)	04 Nov 2020 16:36:27
User opened query 'Per ETRTR, please provide rationale for Unscheduled visit being performed. If related to an AE please ensure Adverse Events page is updated accordingly. ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 22:29:00
User entered '8 Sep 2020'	Joan Siegner (b) (4)	08 Sep 2020 17:53:29

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:38:44

[Physical Exam](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:24
User entered '0'	Joan Siegner (b) (4)	08 Sep 2020 17:53:29

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:38:44

[Vital Signs](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:24
User entered '1'	Joan Siegner (b) (4)	08 Sep 2020 17:53:29

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:38:44

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:24
User entered '0'	Joan Siegner (b) (4)	08 Sep 2020 17:53:29

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:38:44

[Pregnancy Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:24
User entered '0'	Joan Siegner (b) (4)	08 Sep 2020 17:53:29

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:54:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 17:54:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 17:54:17
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:54:04
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User entered '08 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	09 Nov 2020 15:51:56
User entered '8 Sep 2020'	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User entered '08:30'	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 08:30'	System	09 Nov 2020 15:51:56
User entered '8 Sep 2020 08:30'	System	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User entered '97.9' F	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User entered 'Oral (Oral)'	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Pulse (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User closed query 'Per ETRTR, patient may have Bradycardia but no AE is listed for this event. Please confirm if pulse of 50 beats/min is clinically significant and ensure AE page is updated if applicable.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:23:21
Query 'Per ETRTR, patient may have Bradycardia but no AE is listed for this event. Please confirm if pulse of 50 beats/min is clinically significant and ensure AE page is updated if applicable.' answered with 'NCS' (Site from CRA).	Cassandra Zehenny (b) (4)	04 Nov 2020 15:25:51
User opened query 'Per ETRTR, patient may have Bradycardia but no AE is listed for this event. Please confirm if pulse of 50 beats/min is clinically significant and ensure AE page is updated if applicable.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 22:21:42
User entered '50'	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User entered '16'	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User entered '125'	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:19
User entered '81'	Joan Siegner (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 17:54:04

US3552024

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:38:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:06:56
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Sep 2020 16:41:27

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:40:52
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:26
User entered 'USA-US089-2020-mRNA-1273-P301000001'	System	04 Sep 2020 17:13:51
User entered 'New'	(b) (4), (b) (6)	04 Sep 2020 17:13:51

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:05:59
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Non-cardiac chest pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 16:13:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 16:13:19
User closed query 'PCP notes indicate final diagnosis Chest pain, unspecified type. Please reconcile or provide source to support diagnosis Musculoskeletal chest pain ' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 00:48:59
Data point term sent to Coder	System	30 Sep 2020 13:56:35
Query 'PCP notes indicate final diagnosis Chest pain, unspecified type. Please reconcile or provide source to support diagnosis Musculoskeletal chest pain ' answered with 'updated per monitor' (Site from CRA).	Heather Douds (b) (4) (b) (4)	30 Sep 2020 13:56:05
Coding entries removed.	Heather Douds (b) (4) (b) (4)	30 Sep 2020 13:55:57
User entered 'Non-cardiac CHEST PAIN, non-specified' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	30 Sep 2020 13:55:57
User opened query 'PCP notes indicate final diagnosis Chest pain, unspecified type. Please reconcile or provide source to support diagnosis Musculoskeletal chest pain ' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 13:54:58
User closed query 'PV Query: Please consider updating the event term to the final diagnosis/etiology of the chest pain if known. If to remain as chest pain, please state as such. ' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 19:17:22
User closed query 'PV Query: If event term is to remain as chest pain, please consider updating to the type of chest pain (ie cardiac chest pain, non cardiac chest pain). ' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 19:17:19
Query 'PV Query: Please consider updating the event term to the final diagnosis/etiology of the chest pain if known. If to remain as chest pain, please state as such. ' answered with 'done' (Site from Safety).	Heather Douds (b) (4) (b) (4)	15 Sep 2020 16:40:57

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Musculoskeletal chest pain - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 16:00:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 16:00:47
Query 'PV Query: If event term is to remain as chest pain, please consider updating to the type of chest pain (ie cardiac chest pain, non cardiac chest pain). ' answered with 'Updated per query request' (Site from Safety).	Heather Douds (b) (4)	15 Sep 2020 16:00:17
Data point term sent to Coder	System	15 Sep 2020 15:59:58
Coding entries removed.	Heather Douds (b) (4)	15 Sep 2020 15:59:58
User entered 'musculoskeletal CHEST PAIN' reason for change: Per Query Resolution	Heather Douds (b) (4)	15 Sep 2020 15:59:58
User opened query 'PV Query: Please consider updating the event term to the final diagnosis/etiology of the chest pain if known. If to remain as chest pain, please state as such. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:45:48
User opened query 'PV Query: If event term is to remain as chest pain, please consider updating to the type of chest pain (ie cardiac chest pain, non cardiac chest pain). ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:43:56
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 16:53:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 16:53:41
Data point term sent to Coder	System	03 Sep 2020 16:52:47
User entered 'chest pain'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:40:56
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:40:57
User entered 'No (N)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:17:15
User entered 'No (N)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:27:25
User entered '24 Aug 2020'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:27:29
User entered empty.	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:27:31
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 12:42:28
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:17:52
User closed query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 12:44:16
Query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	22 Sep 2020 13:36:44
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Sep 2020 13:36:31
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	22 Sep 2020 13:36:31
User entered '11 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	22 Sep 2020 13:36:06
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Sep 2020 12:43:32
User entered '3 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 12:42:28
User opened query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 11:47:27
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 11:46:02
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'still ongoing at this time' (Site from Safety).	Joan Siegner (b) (4)	19 Sep 2020 11:59:15
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:44:56

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:14:38
User entered empty.	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:41:02
Query 'PV Query: As the event required hospitalization, please consider updating intensity to grade 3. If not, please clarify.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Sep 2020 10:18:13
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Heather Douds (b) (4)	12 Sep 2020 14:38:08
User opened query 'PV Query: As the event required hospitalization, please consider updating intensity to grade 3. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:46:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:41:04
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:41:07
User entered '0'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:41:09
User entered '0'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:41:11
User entered '1'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:17:52
User entered '29 Aug 2020'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:17:54
User entered '30 Aug 2020'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:07
User entered 'No (N)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:09
User entered empty.	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:11
User entered '0'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:13
User entered '0'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:14
User entered '0'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:36
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:38
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:40
User entered 'None (NONE)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:42
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Sep 2020 16:52:17
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	03 Sep 2020 16:52:17
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Sep 2020 16:51:54
User entered '0'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:18:44
User entered '0'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:27:15
User entered '0'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:27:13
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 12:44:24
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	22 Sep 2020 13:36:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	22 Sep 2020 13:36:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 12:43:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 12:42:28
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:45:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:27:09
User entered empty.	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:27:04
User closed query 'Per DM CLR: SAE Narrative contains procedures. However, these are not recorded in the Con Proc eCRF. Update and reconcile records as appropriate. Otherwise, clarify inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:48:30
Query 'Please capture Chest x ray and EKG under con procedures page. ' canceled (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 13:41:47
User opened query 'Please capture Chest x ray and EKG under con procedures page. ' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 13:38:41
Query 'Please capture chest xray (8/29/20, EKG under the con procedures eCRF. ' canceled (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 13:35:55
User opened query 'Please capture chest xray (8/29/20, EKG under the con procedures eCRF. ' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 13:34:32
Query 'Per DM CLR: SAE Narrative contains procedures. However, these are not recorded in the Con Proc eCRF. Update and reconcile records as appropriate. Otherwise, clarify inconsistencies. ' answered with 'EKGs, Chest X rays, stress tests, and labs are diagnostic tests, not procedures. That is why they were not added to the con prec eCRF. Thank you' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 19:32:52
User opened query 'Per DM CLR: SAE Narrative contains procedures. However, these are not recorded in the Con Proc eCRF. Update and reconcile records as appropriate. Otherwise, clarify inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:08:54
User closed query 'PV Query: If available, please provide specific relevant laboratory results and enzyme test with dates performed, units and reference ranges. ' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 19:17:44
User closed query 'PV Query: Please confirm the testing the subject reported (Electrocardiogram, x-rays, laboratory testing, enzyme testing and stress test) was negative. If unable to confirm, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 19:17:40

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 19:17:38
User closed query 'PV Query: Please provide any additional testing to monitor the event with date(s) performed as applicable. ' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 19:17:35
User closed query 'PV Query: Please provide course of event until event resolution. ' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 19:17:31
Query 'PV Query: If available, please provide specific relevant laboratory results and enzyme test with dates performed, units and reference ranges. ' answered with 'Data not available in medical records' (Site from Safety).	Heather Douds (b) (4)	15 Sep 2020 16:55:01
Query 'PV Query: Please confirm the testing the subject reported (Electrocardiogram, x-rays, laboratory testing, enzyme testing and stress test) was negative. If unable to confirm, please state so.' answered with 'done' (Site from Safety).	Heather Douds (b) (4)	15 Sep 2020 16:50:46
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'done' (Site from Safety).	Heather Douds (b) (4)	15 Sep 2020 16:50:41
Query 'PV Query: Please provide any additional testing to monitor the event with date(s) performed as applicable. ' answered with 'no additional testing per medical records' (Site from Safety).	Heather Douds (b) (4)	15 Sep 2020 16:41:40
Query 'PV Query: Please provide course of event until event resolution. ' answered with 'Updated' (Site from Safety).	Heather Douds (b) (4)	15 Sep 2020 16:41:12

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'STATES DEVELOPED CHEST PAIN 24AUG AFTER STARTING A GENERATOR IN HIS GARAGE. PAIN IS INTERMITTENT, COMES WITH SNEEZING OR MOVING A CERTAIN WAY. WENT TO URGENT CARE 29AUG AND SENT TO HOSPITAL WHERE HE WAS ADMITTED OVERNIGHT FOR TESTING AND OBSERVATION. HAD EKG, X-RAYS, LAB WORK, ENZYME TESTS AND STRESS TEST. SUBJECT STATES ALL TESTS WERE NEGATIVE AND HE WAS DISCHARGED AND REFERRED TO HIS PCP. STILL HAVING INTERMITTENT PAIN WITH CERTAIN MOVEMENTS. CBC, CMP, cardiac enzymes and troponins were normal. EKG showed sinus bradycardia. Chest X ray shows no acute cardiopulmonary disease. Normal cardiac exam aside from bradycardia per hospital physician. Stress test results not available but reported to be negative by subject. No surgical interventions, no new medications, no additional treatments per subject.' reason for change: Data Entry Error	Heather Douds (b) (4)	15 Sep 2020 16:40:52
User opened query 'PV Query: If available, please provide specific relevant laboratory results and enzyme test with dates performed, units and reference ranges. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:46:37
User opened query 'PV Query: Please confirm the testing the subject reported (Electrocardiogram, x-rays, laboratory testing, enzyme testing and stress test) was negative. If unable to confirm, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:46:25
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:45:32
User opened query 'PV Query: Please provide any additional testing to monitor the event with date(s) performed as applicable. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:44:35
v6.020 DTW (1102)		
1299 of 1557		

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide course of event until event resolution. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 19:44:18
User entered 'STATES DEVELOPED CHEST PAIN 24AUG AFTER STARTING A GENERATOR IN HIS GARAGE. PAIN IS INTERMITTENT, COMES WITH SNEEZING OR MOVING A CERTAIN WAY. WENT TO URGENT CARE 29AUG AND SENT TO HOSPITAL WHERE HE WAS ADMITTED OVERNIGHT FOR TESTING AND OBSERVATION. HAD EKG, X-RAYS, LAB WORK, ENZYME TESTS AND STRESS TEST. SUBJECT STATES ALL TESTS WERE NEGATIVE AND HE WAS DISCHARGED AND REFERRED TO HIS PCP. STILL HAVING INTERMITTENT PAIN WITH CERTAIN MOVEMENTS.' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 17:49:38
User entered 'States developed chest pain 24AUG after starting a generator in his garage. Pain is intermittent, comes with sneezing or moving a certain way. Went to Urgent Care 29AUG and sent to hospital where he was admitted overnight for testing and observation. Had EKG, X-rays, lab work, enzyme tests and stress test. Subject states all tests were negative and he was discharged and referred to his PCP. Still having intermittent pain with certain movements. Medical records are being requested.'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:57
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 15:43:09
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:43:07
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 17:30:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 17:30:55
Data point term sent to Coder	System	08 Sep 2020 17:29:38
User entered 'seasonal allergies'	Stanley Dublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:58
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:00
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:01
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:03
User entered '18 Aug 2020'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:05
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:07
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 12:43:11
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:08
User entered '21 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 12:43:11
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57
	(b) (4)	

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:10
User entered empty.	Stanley Dublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:14
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:29:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 17:29:05
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	08 Sep 2020 17:29:05
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:28:57
User entered empty.	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:16
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:17
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:19
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:20
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:22
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:23
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:28
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:30
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:31
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:33
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:34
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:36
User entered 'None (NONE)'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:37
User entered '1'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 12:43:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:43
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	08 Sep 2020 17:29:05

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Sep 2020 17:28:57

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:38:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:14:59
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:47:59

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Kenalog 1% topical cream noted as current med per PCP hospital record. Please verify the med is actually used by subject and update conmed page as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 15:43:25
Query 'Kenalog 1% topical cream noted as current med per PCP hospital record. Please verify the med is actually used by subject and update conmed page as needed. Thank you! ' answered with 'Med not currently used by subject. Thank you! ' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 18:30:17
User opened query 'Kenalog 1% topical cream noted as current med per PCP hospital record. Please verify the med is actually used by subject and update conmed page as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 16:23:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 13:41:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	14 Aug 2020 13:41:20
Data point term sent to Coder	System	14 Aug 2020 13:40:49
Coding entries removed.	Joan Siegner (b) (4)	14 Aug 2020 13:40:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 12:51:21

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Aug 2020 12:51:21
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	14 Aug 2020 12:50:21
User entered 'losartan'	Stanley Dublin (b) (4)	14 Aug 2020 12:49:47
	(b) (4)	

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'hypertension' reason for change: Data Entry Error	Joan Siegner (b) (4)	14 Aug 2020 13:40:23
User entered 'high blood pressure'	Stanley Dublin (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '100'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 22:36:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'data is correct' (Site from System).	Stanley Doublin (b) (4)	14 Aug 2020 12:49:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 12:49:47
User entered 'un Jun 2009'	Stanley Doublin (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 13:41:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 13:41:20
Data point term sent to Coder Coding entries removed.	System Joan Siegner (b) (4)	14 Aug 2020 13:40:50 14 Aug 2020 13:40:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:52:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:52:15
Data point term sent to Coder User entered 'amlodipine'	System Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:51:22 14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'hypertension' reason for change: Data Entry Error	Joan Siegner (b) (4)	14 Aug 2020 13:40:36
User entered 'high blood pressure'	Stanley Dublin (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '5'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 22:36:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'data is correct' (Site from System).	Stanley Doublin (b) (4)	14 Aug 2020 12:51:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 12:51:13
User entered 'un UNK 2015'	Stanley Doublin (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'un Jul 2020'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: TIMOLOL MALEATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:24:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:24:20
Data point term sent to Coder	System	06 Oct 2020 13:00:33
Data point term sent to Coder	System	06 Oct 2020 12:57:30
Coding entries removed.	Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:57:05
User entered 'TIMOLOL MALEATE 0.5%' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:57:05
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: TIMOLOL MALEATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 14:18:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 14:18:43
Data point term sent to Coder	System	31 Aug 2020 14:18:03
Coding entries removed.	Heather Douds (b) (4) (b) (4)	31 Aug 2020 14:17:40
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: TIMOLOL MALEATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 08:50:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 08:50:12
Data point term sent to Coder	System	14 Aug 2020 12:57:31
User entered 'timolol maleate'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'glaucoma'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '1'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Other (OTHER)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User closed query ' Per DM CLR: Please review and remove the drug concentration from the unit field. Update Con Med eCRF as appropriate. ' (Site from DM). Query '	(b) (4), (b) (6)	07 Oct 2020 12:30:57
Per DM CLR: Please review and remove the drug concentration from the unit field. Update Con Med eCRF as appropriate. ' answered with 'removed' (Site from DM). User entered 'DROP' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:57:16
User opened query ' Per DM CLR: Please review and remove the drug concentration from the unit field. Update Con Med eCRF as appropriate. ' (Site from DM). User entered 'drop 0.5%'	Stanley Doublin (b) (4) (b) (4), (b) (6)	06 Oct 2020 12:57:05
	(b) (4), (b) (6)	05 Oct 2020 13:29:42
	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:38:44
[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User closed query ' Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Topical or ophthalmic would be more appropriate route for this type of medication. If so, review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:31:50
Query ' Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Topical or ophthalmic would be more appropriate route for this type of medication. If so, review and update as appropriate.' ' answered with 'data corrected' (Site from DM).	Stanley Doublin (b) (4)	06 Oct 2020 13:00:27
User entered 'Topical (TOPICAL)' reason for change: Per Query Resolution	(b) (4)	06 Oct 2020 13:00:19
User opened query ' Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Topical or ophthalmic would be more appropriate route for this type of medication. If so, review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:29:45
User closed query 'Per CDM: Intraocular option is available at drop down however other is selected. Please consider to select Intraocular option and keep field If route of administration is Other, specify as blank else clarify.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 16:28:51
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	31 Aug 2020 14:17:59
Query 'Per CDM: Intraocular option is available at drop down however other is selected. Please consider to select Intraocular option and keep field If route of administration is Other, specify as blank else clarify.' answered with 'Updated per query request' (Site from DM).	Heather Douds (b) (4)	31 Aug 2020 14:17:45
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	31 Aug 2020 14:17:40

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intraocular (INTRAOCULAR)' reason for change: Per Query Resolution	Heather Douds (b) (4)	31 Aug 2020 14:17:40
User opened query 'Per CDM: Intraocular option is available at drop down however other is selected. Please consider to select Intraocular option and keep field If route of administration is Other, specify as blank else clarify.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 03:45:11
User entered 'Other (OTHER)'	Stanley Doublin (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	31 Aug 2020 14:17:59
User entered 'both eyes'	(b) (4)	
	Stanley Dublin (b) (4)	14 Aug 2020 12:57:18
	(b) (4)	

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 22:36:58
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'data is correct' (Site from System).	Stanley Doublin (b) (4)	14 Aug 2020 12:57:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 12:57:18
User entered 'un UNK 2009'	Stanley Doublin (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 13:42:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 13:42:23
Data point term sent to Coder Coding entries removed.	System Joan Siegner (b) (4)	14 Aug 2020 13:41:51 14 Aug 2020 13:41:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:59:20
Data point term sent to Coder User entered 'amlodipine'	System Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:34 14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'hypertension' reason for change: Data Entry Error	Joan Siegner (b) (4)	14 Aug 2020 13:41:24
User entered 'high blood pressure'	Stanley Dublin (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '10'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 22:37:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'data is correct' (Site from System).	Stanley Doublin (b) (4)	14 Aug 2020 12:58:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'un Jul 2020'	System	14 Aug 2020 12:58:27
	Stanley Doublin (b) (4)	14 Aug 2020 12:58:27
	(b) (4)	

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:35:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:35:28
Data point term sent to Coder	System	12 Oct 2020 15:35:00
Data point term sent to Coder	System	12 Oct 2020 15:33:59
User entered 'Influenza Vaccine'	Cassandra Zehenny (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Influenza Prevention'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'injection'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'once (ONCE)'	Cassandra Zehenny (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 15:34:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 15:34:24
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	12 Oct 2020 15:34:24
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 15:33:48
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:31:20
DataPoint Un-verified.	Stanley Doublin (b) (4)	09 Nov 2020 15:52:38
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 15:52:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 15:33:48
	(b) (4)	

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:31:21
DataPoint Un-verified.	Stanley Doublin (b) (4)	09 Nov 2020 15:52:38
User entered '08 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	09 Nov 2020 15:52:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:33:48

US3552024

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:44

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:31
User entered '14 Sep 2020'	Joan Siegner (b) (4)	14 Sep 2020 18:45:36

US3552024

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:44

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:36
User closed query 'Please choose reason " Other" and comment that Subject remains on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you!' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 20:12:15
Query 'Please choose reason " Other" and comment that Subject remains on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you!' answered with 'Updated per query request' (Site from CRA).	Heather Douds (b) (4) (b) (4)	24 Sep 2020 13:27:47
User entered 'Other (OTHER)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	24 Sep 2020 13:27:40
User opened query 'Please choose reason " Other" and comment that Subject remains on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you!' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 15:36:35
Query 'Please choose reason " Other" and comment that Subject remain on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you!' canceled (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 15:36:17
User opened query 'Please choose reason " Other" and comment that Subject remain on the study, but refuses the second vaccination. The option you have entered (Withdrawal of consent) is applicable when subject is off the study completely. Thank you!' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 15:31:51
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Joan Siegner (b) (4)	14 Sep 2020 18:45:36

US3552024

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:44

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:38
User entered 'subject consents for follow-up, but not for second vaccination.'	Joan Siegner (b) (4)	14 Sep 2020 18:45:36

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'USA-US089-2020-MRNA-1273-P301000001'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'frey'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:49
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'MO'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:51
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:03:55
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 16:38:00
User entered 'US' (non-conformant).	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Oct 2020 12:21:30
User entered '5'	System	23 Sep 2020 12:45:54
User entered '4'	System	15 Sep 2020 18:41:21
User entered '3'	System	13 Sep 2020 10:19:03
User entered '2'	System	09 Sep 2020 16:38:15
User entered '1'	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'USA-US089-2020-MRNA-1273-P301000001'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'frey'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:49
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'MO'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:51
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:03:55
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 16:38:00
User entered 'US' (non-conformant).	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Oct 2020 12:21:30
User entered '5'	System	23 Sep 2020 12:45:54
User entered '4'	System	15 Sep 2020 18:41:21
User entered '3'	System	13 Sep 2020 10:19:03
User entered '2'	System	09 Sep 2020 16:38:15
User entered '1'	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:38:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
User entered '04/Sep/2020 13:14'	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:38:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 16:38:00
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'USA-US089-2020-MRNA-1273-P301000001'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'frey'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:49
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'MO'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:51
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:03:55
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 16:38:00
User entered 'US' (non-conformant).	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Oct 2020 12:21:30
User entered '5'	System	23 Sep 2020 12:45:54
User entered '4'	System	15 Sep 2020 18:41:21
User entered '3'	System	13 Sep 2020 10:19:03
User entered '2'	System	09 Sep 2020 16:38:15
User entered '1'	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:38:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
User entered '09/Sep/2020 12:38'	System	09 Sep 2020 16:38:15

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:38:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 10:18:52
User entered '1'	(b) (4), (b) (6)	09 Sep 2020 16:38:15

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'USA-US089-2020-MRNA-1273-P301000001'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'frey'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:49
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:37:08

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'MO'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:51
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:03:55
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 16:38:00
User entered 'US' (non-conformant).	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Oct 2020 12:21:30
User entered '5'	System	23 Sep 2020 12:45:54
User entered '4'	System	15 Sep 2020 18:41:21
User entered '3'	System	13 Sep 2020 10:19:03
User entered '2'	System	09 Sep 2020 16:38:15
User entered '1'	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:38:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
User entered '13/Sep/2020 06:19'	System	13 Sep 2020 10:19:03

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:38:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
User entered '1'	(b) (4), (b) (6)	13 Sep 2020 10:19:03

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'USA-US089-2020-MRNA-1273-P301000001'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'frey'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:49
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'MO'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:51
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:03:55
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 16:38:00
User entered 'US' (non-conformant).	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Oct 2020 12:21:30
User entered '5'	System	23 Sep 2020 12:45:54
User entered '4'	System	15 Sep 2020 18:41:21
User entered '3'	System	13 Sep 2020 10:19:03
User entered '2'	System	09 Sep 2020 16:38:15
User entered '1'	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:38:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
User entered '15/Sep/2020 14:41'	System	15 Sep 2020 18:41:21

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:38:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 12:45:38
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 18:41:21

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'USA-US089-2020-MRNA-1273-P301000001'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'frey'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:49
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'MO'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:51
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:03:55
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 16:38:00
User entered 'US' (non-conformant).	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Oct 2020 12:21:30
User entered '5'	System	23 Sep 2020 12:45:54
User entered '4'	System	15 Sep 2020 18:41:21
User entered '3'	System	13 Sep 2020 10:19:03
User entered '2'	System	09 Sep 2020 16:38:15
User entered '1'	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:38:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
User entered '23/Sep/2020 08:45'	System	23 Sep 2020 12:45:54

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:38:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:21:22
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 12:45:54

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'USA-US089-2020-MRNA-1273-P301000001'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'Yes (Y)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:14:43
User entered 'No (N)'	System	04 Sep 2020 17:13:51

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'frey'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:49
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
Amendment Manager: User entered 'MO'	System	14 Sep 2020 21:51:25

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:51
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08
	(b) (4)	

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:03:55
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 16:38:00
User entered 'US' (non-conformant).	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Oct 2020 12:21:30
User entered '5'	System	23 Sep 2020 12:45:54
User entered '4'	System	15 Sep 2020 18:41:21
User entered '3'	System	13 Sep 2020 10:19:03
User entered '2'	System	09 Sep 2020 16:38:15
User entered '1'	System	04 Sep 2020 17:14:49

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:38:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
User entered '01/Oct/2020 08:21'	System	01 Oct 2020 12:21:30

US3552024

Folder: SAE USA-US089-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:38:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
User entered '1'	(b) (4), (b) (6)	01 Oct 2020 12:21:30