

US3552024 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:07:29

All time stamps listed in this document are displayed in GMT

US3552024

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:27:50

Generated On: 10 Jun 2021 08:07:29

[Participant ID](#)

US3552024

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

US3552024

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3552024

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Were any significant conditions reported?

Yes ☒

No ☐

US3552024

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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
Height (xxx.x)	71 in
Weight (xxx.x)	191.4 lb
BMI (xxx.x)	26.75070 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552024

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

US3552024

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Height	ND - Not Done
Weight	ND - Not Done

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

TIMEPOINT

DAY 2

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

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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 ☒

PRODUCTION RELEASE (v12.003

47 of 1440

EAB) (1725)

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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 ☒

PRODUCTION RELEASE (v12.003

49 of 1440

EAB) (1725)

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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 ☒

PRODUCTION RELEASE (v12.003

53 of 1440

EAB) (1725)

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

55 of 1440

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

57 of 1440

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	14 SEP 2020
Collection time (00:00-23:59)	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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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 _____

Height (derived) _____

Weight (derived) _____

US3552024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

US3552024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 05:01:14
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: 10 Jun 2021 08:07:29

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

Date and time of submission

05 DEC 2020 04:23:13

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 13:23:09
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: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 03:45:54
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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

Date and time of submission

26 DEC 2020 07:32:59

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 19:05:13
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 06:09:42
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 08:29:51
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 07:37:08
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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

Date and time of submission

30 JAN 2021 10:20:34

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 07:52:18
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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 ☐
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):	
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 ☐
Date and time of submission	13 FEB 2021 20:30:30
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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

Date and time of submission

20 FEB 2021 14:58:39

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 02:04:51
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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

Date and time of submission

07 MAR 2021 09:46:38

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: 10 Jun 2021 08:07:29

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

Date and time of submission

13 MAR 2021 05:07:20

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: 10 Jun 2021 08:07:29

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

Date and time of submission

23 MAR 2021 05:10:21

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: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 MAR 2021 00:02:51
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: 10 Jun 2021 08:07:29

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 ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 13:47:01
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: 10 Jun 2021 08:07:29

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

Date and time of submission

10 APR 2021 06:48:02

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: 10 Jun 2021 08:07:29

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 00:03:05
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3552024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:07:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 02:05:07

US3552024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 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 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

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 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 16:49:43

Generated On: 10 Jun 2021 08:07:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:17:52

Generated On: 10 Jun 2021 08:07:29

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 _____

Height (derived) _____

Weight (derived) _____

US3552024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:11:00

Generated On: 10 Jun 2021 08:07:29

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 16:49:43

Generated On: 10 Jun 2021 08:07:29

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	01 MAR 2021
Collection time (00:00-23:59)	09:55 (24 HR)
Collection date and time (derived)	01 MAR 2021 09:55

US3552024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 16:49:43

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 19:38:39

Generated On: 10 Jun 2021 08:07:29

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 APR 2021

Please select one status for the follow-up contact Contact Made ☐ Contact Not Made ☒

Comments CONTACT ATTEMPTED
MULTIPLE TIMES, DISCOVERED
If Contact Not Made, please provide Comments THAT SUBJECT IS IN ETHIOPIA
UNTIL MAY 2022 AND IS
UNABLE TO ACCEPT PHONE
CALLS

US3552024

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 19:38:39

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3552024

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	UNBLND_DECIDE

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:19:39

Generated On: 10 Jun 2021 08:07:29

Date of updated informed consent (dd MMM yyyy)	21 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (dd MMM yyyy)	21 JAN 2021
Participant randomization assignment	mRNA-1273 ☒ Placebo ☐
Actual Dose 1	mRNA-1273 ☒ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☒
Will participant receive mRNA-1273?	Yes ☒ No ☐
Placebo Only Flag	
Continuing with mRNA-1273	1

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	07:45 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 07:45
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 11:05
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 21 JAN 2021

What was the treatment time? (00:00-23:59) 10:35 (24 HR)

Treatment Date and Time (derived) 21 JAN 2021 10:35

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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00-23:59)	07:25 (24 HR)
Collection date and time (derived)	21 JAN 2021 07:25

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	07:30
Collection Date and Time (derived)	21 JAN 2021 07:30

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

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 OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

Is the participant continuing to the next visit?	Yes ☒
	No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

US3552024

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 16:49:43

Generated On: 10 Jun 2021 08:07:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 16:49:43

Generated On: 10 Jun 2021 08:07:29

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 _____

Height (derived) _____

Weight (derived) _____

US3552024

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 16:49:43

Generated On: 10 Jun 2021 08:07:29

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: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 16:49:43

Generated On: 10 Jun 2021 08:07:29

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	01 MAR 2021
Collection time (00:00-23:59)	09:55 (24 HR)
Collection date and time (derived)	01 MAR 2021 09:55

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 21 Feb 2021 17:28:34

Generated On: 10 Jun 2021 08:07:29

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

US3552024

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:27:50

Generated On: 10 Jun 2021 08:07:29

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 ☐
PRODUCTION RELEASE (v12.003 EAB) (1725)	149 of 1440

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 17:27:50

Generated On: 10 Jun 2021 08:07:29

Number of Days in ICU	
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)

Data signed: (b) (4) 21 Feb 2021 17:27:50

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:27:50

Generated On: 10 Jun 2021 08:07:29

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

PRODUCTION RELEASE (v12.003

152 of 1440

EAB) (1725)

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Feb 2021 17:27:50

Generated On: 10 Jun 2021 08:07:29

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	
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: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Feb 2021 17:27:50

Generated On: 10 Jun 2021 08:07:29

AEID

Adverse event

LEFT ARM PAIN IPSILATERAL
TO VACCINATION ARM

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)

21 JAN 2021

Start time (00:00-23:59)

11:00 (24 HR)

AE start date and time (derived)

21 JAN 2021 11:00

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

154 of 1440

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Feb 2021 17:27:50

Generated On: 10 Jun 2021 08:07:29

Number of Days in ICU	
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	
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

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

157 of 1440

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

	Intramuscular	☐
	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)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

159 of 1440

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

	Intramuscular	☐
	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)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

161 of 1440

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

	Intramuscular	☐
	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)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

163 of 1440

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

	Intramuscular	☐
	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)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

165 of 1440

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 17:27:51

Generated On: 10 Jun 2021 08:07:29

	Intramuscular	☒
	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

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3552024

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 17:27:52

Generated On: 10 Jun 2021 08:07:29

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

Data signed: (b) (4) 20 Apr 2021 19:38:39

Generated On: 10 Jun 2021 08:07:29

Date of study discontinuation/completion (dd MMM yyyy) 20 APR 2021

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

SUBJECT WILL BE IN ETHIOPIA UNTIL MAY 2022 AND UNABLE TO COMPLETE SAFETY CALLS AND VISITS DURING THAT TIME

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

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

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)

Data signed: (b) (4) 21 Feb 2021 17:27:53

Generated On: 10 Jun 2021 08:07:29

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: 10 Jun 2021 08:07:29

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'US3552024'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:59:26

US3552024

Form: Participant Creation

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11

US3552024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
DataPoint Un-verified.	(b) (4)	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)	14 Aug 2020 12:36:47
	(b) (4)	

US3552024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:26:14
DataPoint Verified.		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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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 Doublin (b) (4) (b) (4)	14 Aug 2020 12:36:47

US3552024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'SCRN'	System	14 Aug 2020 12:36:47

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:59:27

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '62'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'YEARS'	System	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '62'	System	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Male (M)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:18

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Aug 2020'	System	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '2020'	System	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:01:44

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:59:26

US3552024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'l'	System	13 Aug 2020 17:02:02

US3552024

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:02:02

US3552024

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:07:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:37:43

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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) (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 Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'un Jun 1999'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Jun 1999'	System	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '1999'	System	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	14 Aug 2020 12:38:14

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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) (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.	Coder Import (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) (b) (4)	29 Sep 2020 18:46:05
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 18:46:00
User entered 'bilateral GLAUCOMA' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (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) (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.	Coder Import (b) (4)	14 Aug 2020 12:39:22
Data point term sent to Coder	System	14 Aug 2020 12:39:08

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

[Condition](#)

Audit	User	Time (GMT)
User entered 'glaucoma'	Stanley Dublin (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'un UNK 1999'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Jan 1999'	System	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '1999'	System	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	14 Aug 2020 12:38:37

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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) (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) (b) (4)	14 Aug 2020 12:39:29
User entered 'cataract'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'un Dec 2017'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'un Dec 2017'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Dec 2017'	System	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '2017'	System	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Dec 2017'	System	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '2017'	System	14 Aug 2020 12:39:17

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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).	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 18:46:55
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 18:46:50

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

[Condition](#)

Audit	User	Time (GMT)
User entered 'LASER SURGERY AND CATARACT LENS IMPLANT in right eye' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	29 Sep 2020 18:46:50
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)	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)	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)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'un Dec 2017'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'un Dec 2017'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Dec 2017'	System	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '2017'	System	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Dec 2017'	System	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '2017'	System	14 Aug 2020 12:41:27

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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) (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, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (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) (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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '11 Jun 2009'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Jun 2009'	System	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '2009'	System	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	30 Sep 2020 17:22:49

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Dec 2017'	System	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '2017'	System	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'Dec 2017'	System	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '2017'	System	02 Oct 2020 18:22:39

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '13 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '11:00'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '13 Aug 2020 11:00'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '71' in	(b) (4)	
	Stanley Dublin (b) (4)	14 Aug 2020 12:42:47
	(b) (4)	
DataPoint set to visible.	System	13 Aug 2020 17:02:02

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '191.4' lb	(b) (4) 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: 10 Jun 2021 08:07:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
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: 10 Jun 2021 08:07:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
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: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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) (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) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'bpm'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'breaths/min'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'mmHg'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'mmHg'	System	14 Aug 2020 12:42:47

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23

US3552024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23

US3552024

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:05

US3552024

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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).	System	14 Sep 2020 18:45:48
User entered '13 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:05

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '0'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '0'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:44

US3552024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '13 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:56

US3552024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:43:56

US3552024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'VISIT1'	System	14 Aug 2020 12:43:56

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:59:33

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:29

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) 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: 10 Jun 2021 08:07:29

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:59:33

US3552024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:29

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 16:58:18
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	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: 10 Jun 2021 08:07:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User accepted default value 'Pre-Dose (PREDOSE)'	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: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
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: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'bpm'	System	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '18'	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: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'breaths/min'	System	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'mmHg'	System	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'mmHg'	System	14 Aug 2020 12:46:04

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '13 Aug 2020'	(b) (4) 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: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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) (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) (b) (4)	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
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: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'bpm'	System	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'breaths/min'	System	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'mmHg'	System	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'mmHg'	System	14 Aug 2020 12:46:53

US3552024

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '12:36'	(b) (4), (b) (6)	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered '13 Aug 2020 12:36'	System	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'ONCE'	System	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:48:56

US3552024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '11:45'	Stanley Dublin (b) (4) (b) (4)	14 Aug 2020 12:47:19

US3552024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
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: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:47:42

US3552024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
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: 10 Jun 2021 08:07:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	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: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered empty.	System	14 Aug 2020 12:47:47

US3552024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	Joan Siegner (b) (4)	20 Aug 2020 19:29:16

US3552024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'l'	System	20 Aug 2020 19:29:16

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'Yes (Y)'	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: 10 Jun 2021 08:07:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'Yes (Y)'	System	13 Aug 2020 21:24:24
	System	13 Aug 2020 21:24:24

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '98.2'	System	13 Aug 2020 21:24:24
	System	13 Aug 2020 21:24:24

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'No (N)'	System	13 Aug 2020 21:24:24
	System	13 Aug 2020 21:24:24

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '13 Aug 2020 16:24'	System	13 Aug 2020 21:24:24
	System	13 Aug 2020 21:24:24

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'Yes (Y)'	System	14 Aug 2020 18:01:37
	System	14 Aug 2020 18:01:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '97.1'	System	14 Aug 2020 18:01:37
	System	14 Aug 2020 18:01:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'No (N)'	System	14 Aug 2020 18:01:37
	System	14 Aug 2020 18:01:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '14 Aug 2020 13:01'	System	14 Aug 2020 18:01:37
	System	14 Aug 2020 18:01:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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
	System	15 Aug 2020 17:06:04

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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
	System	15 Aug 2020 17:06:04

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'No (N)'	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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'Yes (Y)'	System	16 Aug 2020 17:22:01
	System	16 Aug 2020 17:22:01

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '97.0'	System	16 Aug 2020 17:22:01
	System	16 Aug 2020 17:22:01

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '16 Aug 2020 12:21'	System	16 Aug 2020 17:22:01
	System	16 Aug 2020 17:22:01

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'Yes (Y)'	System	17 Aug 2020 17:04:37
	System	17 Aug 2020 17:04:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '96.8'	System	17 Aug 2020 17:04:37
	System	17 Aug 2020 17:04:37

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'Yes (Y)'	System	18 Aug 2020 17:11:03
	System	18 Aug 2020 17:11:03

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '96.8'	System	18 Aug 2020 17:11:03
	System	18 Aug 2020 17:11:03

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'No (N)'	System	18 Aug 2020 17:11:03
	System	18 Aug 2020 17:11:03

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '18 Aug 2020 12:11'	System	18 Aug 2020 17:11:03
	System	18 Aug 2020 17:11:03

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '97.0'	System	19 Aug 2020 17:11:49
	System	19 Aug 2020 17:11:49

US3552024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (1)'	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: 10 Jun 2021 08:07:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'No (N)'	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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'No (N)'	System	13 Aug 2020 21:26:33
	System	13 Aug 2020 21:26:33

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '13 Aug 2020 16:26'	System	13 Aug 2020 21:26:33
	System	13 Aug 2020 21:26:33

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '16 Aug 2020 12:22'	System	16 Aug 2020 17:22:36
	System	16 Aug 2020 17:22:36

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '18 Aug 2020 12:11'	System	18 Aug 2020 17:11:42
	System	18 Aug 2020 17:11:42

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'No (N)'	System	19 Aug 2020 17:12:14
	System	19 Aug 2020 17:12:14

US3552024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	13 Aug 2020 18:12:46
	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	13 Aug 2020 18:12:46
	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	13 Aug 2020 18:12:46
	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	13 Aug 2020 18:12:46
	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	13 Aug 2020 18:12:46
	System	13 Aug 2020 18:12:46

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	13 Aug 2020 21:27:41
	System	13 Aug 2020 21:27:41

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'No interference with activity (1)'	System	14 Aug 2020 18:03:25
	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	14 Aug 2020 18:03:25
	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	14 Aug 2020 18:03:25
	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	14 Aug 2020 18:03:25
	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	14 Aug 2020 18:03:25
	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	14 Aug 2020 18:03:25
	System	14 Aug 2020 18:03:25

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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-acfc-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: 10 Jun 2021 08:07:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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-acfc-c75b42a4a871' User entered 'None (0)'	System	15 Aug 2020 17:07:50
	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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-acfc-c75b42a4a871' User entered 'None (0)'	System	15 Aug 2020 17:07:50
	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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-acfc-c75b42a4a871' User entered 'None (0)'	System	15 Aug 2020 17:07:50
	System	15 Aug 2020 17:07:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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-acfc-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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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-acfc-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: 10 Jun 2021 08:07:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	16 Aug 2020 17:23:14
	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	16 Aug 2020 17:23:14
	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	16 Aug 2020 17:23:14
	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	16 Aug 2020 17:23:14
	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	16 Aug 2020 17:23:14
	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '16 Aug 2020 12:23'	System	16 Aug 2020 17:23:14
	System	16 Aug 2020 17:23:14

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	17 Aug 2020 17:05:37
	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	17 Aug 2020 17:05:37
	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	17 Aug 2020 17:05:37
	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	17 Aug 2020 17:05:37
	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	17 Aug 2020 17:05:37
	System	17 Aug 2020 17:05:37

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	18 Aug 2020 17:12:15
	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	18 Aug 2020 17:12:15
	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	18 Aug 2020 17:12:15
	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	18 Aug 2020 17:12:15
	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	18 Aug 2020 17:12:15
	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	18 Aug 2020 17:12:15
	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '18 Aug 2020 12:12'	System	18 Aug 2020 17:12:15
	System	18 Aug 2020 17:12:15

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	19 Aug 2020 17:12:50
	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	19 Aug 2020 17:12:50
	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'None (0)'	System	19 Aug 2020 17:12:50
	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '19 Aug 2020 12:12'	System	19 Aug 2020 17:12:50
	System	19 Aug 2020 17:12:50

US3552024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '20 Aug 2020 12:04'	System	20 Aug 2020 17:04:32
	System	20 Aug 2020 17:04:32

US3552024

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:07:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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) (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) (b) (4)	27 Aug 2020 16:32:59
User entered '20 Aug 2020'	Joan Siegner (b) (4) (b) (4)	20 Aug 2020 19:29:39

US3552024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4) [REDACTED]	20 Aug 2020 19:29:39

US3552024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4)	20 Aug 2020 19:29:39

US3552024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:58:53

US3552024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'l'	System	27 Aug 2020 15:58:53

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:59:06

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '27 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:59:06

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:59:06

US3552024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'l'	System	03 Sep 2020 16:40:35

US3552024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '03 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 15:51:02
User entered '3 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	03 Sep 2020 16:41:08

US3552024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4) [REDACTED]	03 Sep 2020 16:41:08

US3552024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	03 Sep 2020 16:41:08

US3552024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:44:55

US3552024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'l'	System	14 Sep 2020 18:44:55

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:45:48

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '14 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 18:45:48

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Clinic (Clinic)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 18:45:48

US3552024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'VISIT2'	System	14 Sep 2020 18:45:48

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
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: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '14 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '12:00'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
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: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '55'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered 'bpm'	System	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '18'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
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: 10 Jun 2021 08:07:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '138'	Joan Siegner (b) (4) (b) (4)	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered 'mmHg'	System	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '86'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered 'mmHg'	System	14 Sep 2020 18:46:31

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	22 Sep 2020 12:40:23

US3552024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:38

US3552024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'subject willing to continue follow up, but not willing to have second vaccination'	Joan Siegner (b) (4)	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered empty.	System	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4)	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered empty.	System	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered empty.	System	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered empty.	System	14 Sep 2020 18:47:15

US3552024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '14 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 18:47:33

US3552024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '12:02'	Joan Siegner (b) (4) (b) (4)	14 Sep 2020 18:47:33

US3552024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
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: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '14 Sep 2020'	(b) (4) 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: 10 Jun 2021 08:07:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
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: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '12:05'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
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: 10 Jun 2021 08:07:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
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: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered empty.	System	14 Sep 2020 18:47:47

US3552024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'I'	System	22 Sep 2020 12:40:46

US3552024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:55

US3552024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:55

US3552024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:40:55

US3552024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:48:54

US3552024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'l'	System	28 Sep 2020 16:48:54

US3552024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '28 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:49:06

US3552024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:49:06

US3552024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:49:06

US3552024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'l'	System	06 Oct 2020 12:58:17

US3552024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	09 Nov 2020 15:51:30
User entered '5 Oct 2020'	(b) (4)	
	Stanley Dublin (b) (4)	06 Oct 2020 12:58:26
	(b) (4)	

US3552024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	06 Oct 2020 12:58:26

US3552024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'l'	System	12 Oct 2020 16:33:50

US3552024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '12 Oct 2020'	(b) (4) Joan Siegner (b) (4)	12 Oct 2020 16:34:01

US3552024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Clinic (Clinic)'	Joan Siegner (b) (4) [REDACTED]	12 Oct 2020 16:34:01

US3552024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered 'VISIT3'	System	12 Oct 2020 16:34:01

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered empty.	System	12 Oct 2020 16:34:12

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11

US3552024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11

US3552024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	12 Oct 2020 16:34:19

US3552024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Joan Siegner (b) (4) [REDACTED]	12 Oct 2020 16:34:19

US3552024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '12 Oct 2020'	(b) (4) Joan Siegner (b) (4)	12 Oct 2020 16:34:31

US3552024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered '10:09'	Joan Siegner (b) (4) (b) (4)	12 Oct 2020 16:34:31

US3552024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
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: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:11
User entered 'I'	System	10 Nov 2020 13:18:44

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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'	System	15 Oct 2020 20:25:55
User entered '15 Oct 2020 15:25:52'	System	15 Oct 2020 20:25:55

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '20 Oct 2020 02:11:26'	System	20 Oct 2020 07:11:31
	System	20 Oct 2020 07:11:31

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered '12 Nov 2020 08:55:22'	System	12 Nov 2020 14:55:44
	System	12 Nov 2020 14:55:44

US3552024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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' User entered 'No (N)'	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: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:52:14
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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' User entered 'No (N)'	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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-28T05:01:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '144155d2-b207-42e8-b531-43c3d8cb57c2'	System	28 Nov 2020 11:01:16
User entered 'No (N)'	System	28 Nov 2020 11:01:16

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-28T05:01:03', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '144155d2-b207-42e8-b531-43c3d8cb57c2'	System	28 Nov 2020 11:01:16
User entered 'No (N)'	System	28 Nov 2020 11:01:16

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-11-28T05:01:14', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '144155d2-b207-42e8-b531-43c3d8cb57c2'	System	28 Nov 2020 11:01:16
User entered '28 Nov 2020 05:01:14'	System	28 Nov 2020 11:01:16

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-05T04:22:59', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '015d7a06-4af6-48c5-851a-12e75ac4d3dd'	System	05 Dec 2020 10:23:15
User entered 'No (N)'	System	05 Dec 2020 10:23:15

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-05T04:23:08', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '015d7a06-4af6-48c5-851a-12e75ac4d3dd'	System	05 Dec 2020 10:23:15
User entered 'No (N)'	System	05 Dec 2020 10:23:15

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-05T04:23:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '015d7a06-4af6-48c5-851a-12e75ac4d3dd'	System	05 Dec 2020 10:23:15
User entered '05 Dec 2020 04:23:13'	System	05 Dec 2020 10:23:15

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-13T13:23:03', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '14123c94-6959-4eb5-99e3-61c463713931'	System	13 Dec 2020 19:23:11
User entered 'No (N)'	System	13 Dec 2020 19:23:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-13T13:23:05', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '14123c94-6959-4eb5-99e3-61c463713931'	System	13 Dec 2020 19:23:11
User entered 'No (N)'	System	13 Dec 2020 19:23:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-13T13:23:09', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '14123c94-6959-4eb5-99e3-61c463713931' User entered '13 Dec 2020 13:23:09'	System	13 Dec 2020 19:23:11
	System	13 Dec 2020 19:23:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-19T03:45:25', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '84a917e7-2822-40b7-89bc-15eb361ac458'	System	19 Dec 2020 09:45:57
User entered 'No (N)'	System	19 Dec 2020 09:45:57

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-19T03:45:40', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '84a917e7-2822-40b7-89bc-15eb361ac458'	System	19 Dec 2020 09:45:57
User entered 'No (N)'	System	19 Dec 2020 09:45:57

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-19T03:45:54', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '84a917e7-2822-40b7-89bc-15eb361ac458' User entered '19 Dec 2020 03:45:54'	System	19 Dec 2020 09:45:57
	System	19 Dec 2020 09:45:57

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-26T07:32:50', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '6a0cfd03-4711-40f6-95f9-c834dde7d536'	System	26 Dec 2020 13:33:02
User entered 'No (N)'	System	26 Dec 2020 13:33:02

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-26T07:32:56', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '6a0cfd03-4711-40f6-95f9-c834dde7d536'	System	26 Dec 2020 13:33:02
User entered 'No (N)'	System	26 Dec 2020 13:33:02

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2020-12-26T07:32:59', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '6a0cfd03-4711-40f6-95f9-c834dde7d536'	System	26 Dec 2020 13:33:02
User entered '26 Dec 2020 07:32:59'	System	26 Dec 2020 13:33:02

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-03T19:05:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cd2e3040-8f13-42e9-b9d0-99b3268bae28'	System	04 Jan 2021 01:05:17
User entered 'No (N)'	System	04 Jan 2021 01:05:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-03T19:05:05', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cd2e3040-8f13-42e9-b9d0-99b3268bae28'	System	04 Jan 2021 01:05:17
User entered 'No (N)'	System	04 Jan 2021 01:05:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-03T19:05:13', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cd2e3040-8f13-42e9-b9d0-99b3268bae28' User entered '03 Jan 2021 19:05:13'	System	04 Jan 2021 01:05:17
	System	04 Jan 2021 01:05:17

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-09T06:09:28', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a378f5d7-99f7-499b-8d79-8836fd8df267'	System	09 Jan 2021 12:09:47
User entered 'No (N)'	System	09 Jan 2021 12:09:47

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-09T06:09:34', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a378f5d7-99f7-499b-8d79-8836fd8df267'	System	09 Jan 2021 12:09:47
User entered 'No (N)'	System	09 Jan 2021 12:09:47

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-09T06:09:42', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a378f5d7-99f7-499b-8d79-8836fd8df267' User entered '09 Jan 2021 06:09:42'	System	09 Jan 2021 12:09:47
	System	09 Jan 2021 12:09:47

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-17T08:29:39', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '2b6f7555-77a6-4477-b872-5c6202d4e2ee'	System	17 Jan 2021 14:29:54
User entered 'No (N)'	System	17 Jan 2021 14:29:54

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-17T08:29:41', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '2b6f7555-77a6-4477-b872-5c6202d4e2ee'	System	17 Jan 2021 14:29:54
User entered 'No (N)'	System	17 Jan 2021 14:29:54

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-17T08:29:51', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '2b6f7555-77a6-4477-b872-5c6202d4e2ee' User entered '17 Jan 2021 08:29:51'	System	17 Jan 2021 14:29:54
	System	17 Jan 2021 14:29:54

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-23T07:36:53', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '7bc767d2-5b23-487c-ab18-eaf4f028b7aa'	System	23 Jan 2021 13:37:11
User entered 'No (N)'	System	23 Jan 2021 13:37:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-23T07:37:01', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '7bc767d2-5b23-487c-ab18-eaf4f028b7aa'	System	23 Jan 2021 13:37:11
User entered 'No (N)'	System	23 Jan 2021 13:37:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-23T07:37:08', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '7bc767d2-5b23-487c-ab18-eaf4f028b7aa' User entered '23 Jan 2021 07:37:08'	System	23 Jan 2021 13:37:11
	System	23 Jan 2021 13:37:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-30T10:20:26', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c6fce501-1235-4d35-8d88-ecc378e0cfc0' User entered 'No (N)'	System	30 Jan 2021 16:20:38
	System	30 Jan 2021 16:20:38

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-30T10:20:31', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c6fce501-1235-4d35-8d88-ecc378e0cfc0'	System	30 Jan 2021 16:20:38
User entered 'No (N)'	System	30 Jan 2021 16:20:38

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-01-30T10:20:34', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c6fce501-1235-4d35-8d88-ecc378e0cfc0' User entered '30 Jan 2021 10:20:34'	System	30 Jan 2021 16:20:38
	System	30 Jan 2021 16:20:38

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-06T07:52:01', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3edb53a5-4886-4821-9313-6f7c367c6b53' User entered 'No (N)'	System	06 Feb 2021 13:52:24
	System	06 Feb 2021 13:52:24

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-06T07:52:14', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3edb53a5-4886-4821-9313-6f7c367c6b53'	System	06 Feb 2021 13:52:24
User entered 'No (N)'	System	06 Feb 2021 13:52:24

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-06T07:52:18', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '3edb53a5-4886-4821-9313-6f7c367c6b53' User entered '06 Feb 2021 07:52:18'	System	06 Feb 2021 13:52:24
	System	06 Feb 2021 13:52:24

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-13T20:28:37', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '1a850e52-c2d6-4f4a-aaa9-f331f3e0e000'	System	14 Feb 2021 02:32:11
User entered 'Yes (Y)'	System	14 Feb 2021 02:32:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-13T20:28:43', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '1a850e52-c2d6-4f4a-aaa9-f331f3e0e000'	System	14 Feb 2021 02:32:11
User entered 'No (N)'	System	14 Feb 2021 02:32:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-13T20:28:52', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '1a850e52-c2d6-4f4a-aaa9-f331f3e0e000'	System	14 Feb 2021 02:32:11
User entered 'No (N)'	System	14 Feb 2021 02:32:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-13T20:30:20', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '1a850e52-c2d6-4f4a-aaa9-f331f3e0e000'	System	14 Feb 2021 02:32:11
User entered 'No (N)'	System	14 Feb 2021 02:32:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-13T20:30:30', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '1a850e52-c2d6-4f4a-aaa9-f331f3e0e000'	System	14 Feb 2021 02:32:11
User entered '13 Feb 2021 20:30:30'	System	14 Feb 2021 02:32:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-20T14:58:29', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c7f1e4b5-a907-4fde-bbbb-ce480970c6ca'	System	20 Feb 2021 20:58:40
User entered 'No (N)'	System	20 Feb 2021 20:58:40

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-20T14:58:35', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c7f1e4b5-a907-4fde-bbbb-ce480970c6ca'	System	20 Feb 2021 20:58:40
User entered 'No (N)'	System	20 Feb 2021 20:58:40

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-20T14:58:39', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c7f1e4b5-a907-4fde-bbbb-ce480970c6ca'	System	20 Feb 2021 20:58:40
User entered '20 Feb 2021 14:58:39'	System	20 Feb 2021 20:58:40

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-27T20:04:38-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '7558fb88-87a8-4c0f-a91a-9e1e09184dab'	System	28 Feb 2021 02:10:29
User entered 'No (N)'	System	28 Feb 2021 02:10:29

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-27T20:04:47-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '7558fb88-87a8-4c0f-a91a-9e1e09184dab'	System	28 Feb 2021 02:10:29
User entered 'No (N)'	System	28 Feb 2021 02:10:29

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-27T20:04:51-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '7558fb88-87a8-4c0f-a91a-9e1e09184dab' User entered '28 Feb 2021 02:04:51'	System	28 Feb 2021 02:10:29
	System	28 Feb 2021 02:10:29

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-07T09:46:32-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '2a9e3766-eb38-4eb1-a87a-346389f49fb9'	System	07 Mar 2021 15:46:42
User entered 'No (N)'	System	07 Mar 2021 15:46:42

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-07T09:46:34-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '2a9e3766-eb38-4eb1-a87a-346389f49fb9'	System	07 Mar 2021 15:46:42
User entered 'No (N)'	System	07 Mar 2021 15:46:42

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-07T09:46:38-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '2a9e3766-eb38-4eb1-a87a-346389f49fb9' User entered '07 Mar 2021 09:46:38'	System	07 Mar 2021 15:46:42
	System	07 Mar 2021 15:46:42

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-13T05:07:03-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'f85dea11-fa38-48ab-a04e-36bbf4866e5c'	System	13 Mar 2021 11:07:24
User entered 'No (N)'	System	13 Mar 2021 11:07:24

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-13T05:07:10-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'f85dea11-fa38-48ab-a04e-36bbf4866e5c'	System	13 Mar 2021 11:07:24
User entered 'No (N)'	System	13 Mar 2021 11:07:24

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-13T05:07:20-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'f85dea11-fa38-48ab-a04e-36bbf4866e5c' User entered '13 Mar 2021 05:07:20'	System	13 Mar 2021 11:07:24
	System	13 Mar 2021 11:07:24

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-23T05:10:16+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '4c28df43-d9c6-47ab-95f3-cfae954a3023'	System	26 Mar 2021 21:02:44
User entered 'No (N)'	System	26 Mar 2021 21:02:44

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-23T05:10:18+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '4c28df43-d9c6-47ab-95f3-cfae954a3023'	System	26 Mar 2021 21:02:44
User entered 'No (N)'	System	26 Mar 2021 21:02:44

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-23T05:10:21+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '4c28df43-d9c6-47ab-95f3-cfae954a3023' User entered '23 Mar 2021 05:10:21'	System	26 Mar 2021 21:02:44
	System	26 Mar 2021 21:02:44

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-27T00:02:45+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cabd96e6-6079-4949-a6b3-a290bf32d3bf' User entered 'No (N)'	System	26 Mar 2021 21:02:55
	System	26 Mar 2021 21:02:55

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-27T00:02:47+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cabd96e6-6079-4949-a6b3-a290bf32d3bf'	System	26 Mar 2021 21:02:55
User entered 'No (N)'	System	26 Mar 2021 21:02:55

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-03-27T00:02:51+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'cabd96e6-6079-4949-a6b3-a290bf32d3bf' User entered '27 Mar 2021 00:02:51'	System	26 Mar 2021 21:02:55
	System	26 Mar 2021 21:02:55

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-03T13:45:50+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a219cf69-c021-4c72-b18f-5620d239e98b'	System	03 Apr 2021 10:47:11
User entered 'No (N)'	System	03 Apr 2021 10:47:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-03T13:46:21+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a219cf69-c021-4c72-b18f-5620d239e98b'	System	03 Apr 2021 10:47:11
User entered 'Yes (Y)'	System	03 Apr 2021 10:47:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-03T13:46:33+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a219cf69-c021-4c72-b18f-5620d239e98b'	System	03 Apr 2021 10:47:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Apr 2021 10:47:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-03T13:47:01+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'a219cf69-c021-4c72-b18f-5620d239e98b' User entered '03 Apr 2021 13:47:01'	System	03 Apr 2021 10:47:11
	System	03 Apr 2021 10:47:11

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-10T06:47:36+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c0237add-62ba-4583-966c-16934188ccd6' User entered 'No (N)'	System	10 Apr 2021 03:48:10
	System	10 Apr 2021 03:48:10

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-10T06:47:59+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c0237add-62ba-4583-966c-16934188ccd6'	System	10 Apr 2021 03:48:10
User entered 'No (N)'	System	10 Apr 2021 03:48:10

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-10T06:48:02+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: 'c0237add-62ba-4583-966c-16934188ccd6' User entered '10 Apr 2021 06:48:02'	System	10 Apr 2021 03:48:10
	System	10 Apr 2021 03:48:10

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-17T00:02:51+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '40427f6e-9f89-4cc6-b554-2024a45ef0f2'	System	16 Apr 2021 21:03:09
User entered 'No (N)'	System	16 Apr 2021 21:03:09

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-17T00:03:02+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '40427f6e-9f89-4cc6-b554-2024a45ef0f2'	System	16 Apr 2021 21:03:09
User entered 'No (N)'	System	16 Apr 2021 21:03:09

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-04-17T00:03:05+03:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '40427f6e-9f89-4cc6-b554-2024a45ef0f2'	System	16 Apr 2021 21:03:09
User entered '17 Apr 2021 00:03:05'	System	16 Apr 2021 21:03:09

US3552024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.		02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:25:36
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:07:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:00:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-27T20:05:02-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '6c8286a3-fd65-4026-bae4-34c9bbcec359'	System	28 Feb 2021 02:11:09
User entered 'No (N)'	System	28 Feb 2021 02:11:09

US3552024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:07:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:00:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B788D29-CAA3-44DF-8294-F30B630C60BB)', Time: '2021-02-27T20:05:07-06:00', User OID: 'PatientReportedOutcome (US3552024)', ODM File OID: '6c8286a3-fd65-4026-bae4-34c9bbcec359' User entered '28 Feb 2021 02:05:07'	System	28 Feb 2021 02:11:09
	System	28 Feb 2021 02:11:09

US3552024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '09 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 13:18:56

US3552024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 13:18:56

US3552024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 13:18:56

US3552024

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Dec 2020 13:46:06

US3552024

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:11:09
User entered 'l'	System	15 Dec 2020 13:46:06

US3552024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Dec 2020 13:46:15

US3552024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '14 Dec 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Dec 2020 13:46:15

US3552024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Dec 2020 13:46:15

US3552024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Dec 2020 13:46:15

US3552024

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Jan 2021 15:19:14

US3552024

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered 'l'	System	12 Jan 2021 15:19:14

US3552024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Jan 2021 15:19:26

US3552024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered '11 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	12 Jan 2021 15:19:26

US3552024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'Contact Made (CONTACT MADE)'	Cassandra Zehenny (b) (4) (b) (4)	12 Jan 2021 15:19:26

US3552024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Jan 2021 15:19:26

US3552024

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 17:20:09

US3552024

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered 'l'	System	08 Feb 2021 17:20:09

US3552024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 17:20:19

US3552024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '08 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 17:20:19

US3552024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 17:20:19

US3552024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 17:20:19

US3552024

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 20:58:41

US3552024

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered 'l'	System	11 Feb 2021 20:58:41

US3552024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:33:52

US3552024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered '01 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:33:52

US3552024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:33:52

US3552024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered 'VISIT4'	System	01 Mar 2021 16:33:52

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered empty.	System	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered empty.	System	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered empty.	System	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered empty.	System	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered empty.	System	29 Mar 2021 19:50:49

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08

US3552024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08

US3552024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:11:00
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:51:51
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:51:34
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:51:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:49:43
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 16:33:59

US3552024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	30 Mar 2021 19:51:51
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	30 Mar 2021 19:51:34
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:33:59

US3552024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:34:11

US3552024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered '01 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:34:11

US3552024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered '09:55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:34:11

US3552024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered '01 Mar 2021 09:55'	System	01 Mar 2021 16:34:11

US3552024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:34:39

US3552024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:23:08
User entered 'I'	System	01 Mar 2021 16:34:39

US3552024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:39
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	20 Apr 2021 16:30:10

US3552024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:39
User entered '12 Apr 2021'	(b) (4) Cassandra Zehenny (b) (4)	20 Apr 2021 16:30:10

US3552024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	20 Apr 2021 19:38:39
User entered 'Contact Not Made (CONTACT NOT MADE)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 16:30:10

US3552024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:39
User entered 'contact attempted multiple times, discovered that subject is in ethiopia until May 2022 and is unable to accept phone calls'	(b) (4) Cassandra Zehenny (b) (4)	20 Apr 2021 16:30:10

US3552024

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:39
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	20 Apr 2021 16:30:15

US3552024

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered empty.	System	20 Apr 2021 16:30:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:48:16

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:48:16

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:48:16

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 18:48:16

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:19:39
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:43:50

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:19:39
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:43:50

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Doublin (b) (4)	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Doublin (b) (4)	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Not Administered (NA)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:07:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'I'	System	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	21 Jan 2021 18:49:15
DataPoint set to visible.	System	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	21 Jan 2021 18:49:15
DataPoint set to visible.	System	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '07:45'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '21 Jan 2021 07:45'	System	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '98.6' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Oral (Oral)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'bpm'	System	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'breaths/min'	System	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '160'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'mmHg'	System	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '97'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'mmHg'	System	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:15

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered empty.	System	21 Jan 2021 18:49:15
DataPoint set to visible.	System	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '11:05'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '21 Jan 2021 11:05'	System	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '97.4' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '50'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'bpm'	System	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'breaths/min'	System	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '157'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'mmHg'	System	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '89'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'mmHg'	System	21 Jan 2021 18:49:44

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:52

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:49:52

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:33

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:33

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered empty.	Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:50:33

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'mRNA-1273'	System	21 Jan 2021 18:50:33
DataPoint set to visible.	System	21 Jan 2021 18:48:41

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:33

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '10:35'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:33

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '21 Jan 2021 10:35'	System	21 Jan 2021 18:50:33

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 18:50:33

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'ONCE'	System	21 Jan 2021 18:50:33

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'INTRAMUSCULAR'	System	21 Jan 2021 18:50:33

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:47

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:47

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '07:25'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:47

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '21 Jan 2021 07:25'	System	21 Jan 2021 18:50:47

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:56

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:56

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:07:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '07:30'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 18:50:56

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:07:29

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered '21 Jan 2021 07:30'	System	21 Jan 2021 18:50:56

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Jan 2021 17:16:38

US3552024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:23
User entered 'I'	System	28 Jan 2021 17:16:38

US3552024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Jan 2021 17:18:30

US3552024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered '28 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Jan 2021 17:18:30

US3552024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4)	28 Jan 2021 17:18:30

US3552024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Jan 2021 17:18:30

US3552024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 20:58:35

US3552024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:51
User entered 'l'	System	11 Feb 2021 20:58:35

US3552024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:29

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:51
User entered 'I'	System	11 Feb 2021 20:58:35
DataPoint set to visible.	System	11 Feb 2021 20:58:35

US3552024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:06

US3552024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered '01 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:06

US3552024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:06

US3552024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User entered 'OLD29'	System	01 Mar 2021 16:31:06

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User entered empty.	System	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User entered empty.	System	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User entered empty.	System	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User entered empty.	System	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User entered empty.	System	01 Mar 2021 16:31:50

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48

US3552024

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48

US3552024

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:55

US3552024

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:31:55

US3552024

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:32:08

US3552024

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User closed query 'Per GCL Lab Recon:LB4 Immuno: Response is not clear, please kindly confirm the correct visit label for this sample dated 01 MAR 2021,if its OL-D29 or OL-D57 as its updated under OL-D57(OL-3) in PPD GCL and here it is updated under OL-D29(OL-2).Thank you.' (Site from DM).		18 Apr 2021 10:02:27
Query 'Per GCL Lab Recon:LB4 Immuno: Response is not clear, please kindly confirm the correct visit label for this sample dated 01 MAR 2021,if its OL-D29 or OL-D57 as its updated under OL-D57(OL-3) in PPD GCL and here it is updated under OL-D29(OL-2).Thank you.' answered with 'subject received first dose under Part A and second dose of vaccine in open label part B. So his OL'29 was not a vaccination date, but blood was drawn as if OL-D57' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4) 01 Apr 2021 16:00:37
User opened query 'Per GCL Lab Recon:LB4 Immuno: Response is not clear, please kindly confirm the correct visit label for this sample dated 01 MAR 2021,if its OL-D29 or OL-D57 as its updated under OL-D57(OL-3) in PPD GCL and here it is updated under OL-D29(OL-2).Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 08:49:08
User closed query 'Per GCL Lab Recon:LB4 Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 01 Mar 2021, as it is updated under OL-D29 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you.' (Site from DM).		31 Mar 2021 14:46:55

US3552024

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Recon:LB4 Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 01 Mar 2021, as it is updated under OL-D29 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you.' answered with '01March2021 is correct. please enter query into Prelcarus if there is a change needed. thank you. ' (Site from DM).	Cassandra Zehenny (b) (4)	15 Mar 2021 15:42:26
User opened query 'Per GCL Lab Recon:LB4 Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 01 Mar 2021, as it is updated under OL-D29 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 14:51:55
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered '01 Mar 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 16:32:08

US3552024

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:43
User entered '09:55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:32:08

US3552024

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:48
User entered '01 Mar 2021 09:55'	System	01 Mar 2021 16:32:08

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 08:07:29

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:11:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
DataPoint Verified.	(b) (4)	
	(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).		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).	(b) (4)	
	Cassandra Zehenny (b) (4)	04 Nov 2020 16:36:27
	(b) (4)	
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: 10 Jun 2021 08:07:29

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:11:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:11:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
DataPoint Verified.	(b) (4)	11 Nov 2020 15:34:24
User entered 'l'	Joan Siegner (b) (4)	08 Sep 2020 17:53:29

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 08:07:29

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:11:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:11:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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) (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) (b) (4)	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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) (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: 10 Jun 2021 08:07:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
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: 10 Jun 2021 08:07:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:28:35
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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).		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) (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: 10 Jun 2021 08:07:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User entered 'bpm'	System	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User entered 'breaths/min'	System	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User entered 'mmHg'	System	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:28:35
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: 10 Jun 2021 08:07:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02
User entered 'mmHg'	System	08 Sep 2020 17:54:04

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02

US3552024

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:12:02

US3552024

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:07:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Adverse event](#)

Audit	User	Time (GMT)
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)	15 Sep 2020 16:40:57
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

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'chest pain'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:07:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:27:29
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:27:29
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered empty.	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:27:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 12:42:28
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	22 Sep 2020 12:42:28
	(b) (4)	
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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). 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)	23 Sep 2020 12:44:16
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 13:36:44
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) (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).		21 Sep 2020 11:46:02

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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). 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). User entered empty.	Joan Siegner (b) (4) (b) (4), (b) (6) Joan Siegner (b) (4)	19 Sep 2020 11:59:15 11 Sep 2020 19:44:56 03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered empty.	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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) (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: 10 Jun 2021 08:07:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	30 Sep 2020 13:41:09
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 13:41:09
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 13:41:11
User entered 'l'	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:07:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:17:54
User entered '30 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 16:51:54
	Joan Siegner (b) (4)	

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:07:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:18:11
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:18:11
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:18:13
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:18:13
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:18:14
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:18:14
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:18:36
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Oct 2020 20:18:36
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:18:38
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Sep 2020 16:51:54
	Joan Siegner (b) (4)	

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:18:40
User entered 'None (NONE)'	(b) (4), (b) (6)	12 Oct 2020 20:18:40
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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).	(b) (4), (b) (6)	03 Sep 2020 16:52:17
User entered '1' reason for change: Data Entry Error	System	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).	Joan Siegner (b) (4)	03 Sep 2020 16:52:17
User entered '0'	System	03 Sep 2020 16:51:54
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:18:44
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:18:44
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:27:15
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:27:15
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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 Dublin (b) (4)	22 Sep 2020 12:43:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Dublin (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: 10 Jun 2021 08:07:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:27:09
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:27:09
	Joan Siegner (b) (4)	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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).		05 Oct 2020 08:48:30
Query 'Please capture Chest x ray and EKG under con procedures page. ' canceled (Site from CRA).		30 Sep 2020 13:41:47
User opened query 'Please capture Chest x ray and EKG under con procedures page. ' (Site from CRA).		30 Sep 2020 13:38:41
Query 'Please capture chest xray (8/29/20, EKG under the con procedures eCRF. ' canceled (Site from CRA).		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).		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).		15 Sep 2020 19:17:44

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Narrative](#)

Audit	User	Time (GMT)
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
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).		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).		15 Sep 2020 19:17:35
User closed query 'PV Query: Please provide course of event until event resolution. ' (Site from Safety).		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

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Narrative](#)

Audit	User	Time (GMT)
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
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.	Heather Douds (b) (4)	15 Sep 2020 16:40:52
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		
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).		11 Sep 2020 19:46:25

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Narrative](#)

Audit	User	Time (GMT)
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).		11 Sep 2020 19:44:35
User opened query 'PV Query: Please provide course of event until event resolution. ' (Site from Safety).		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: 10 Jun 2021 08:07:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered 'I'	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered '1'	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered '0'	System	03 Sep 2020 16:51:54

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	11 Nov 2020 15:26:57
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 15:43:09
DataPoint Verified.		30 Oct 2020 15:43:07
User coded data point as SOC: Immune system disorders, HLGT: 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.	(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 Doublin (b) (4)	08 Sep 2020 17:28:57
	(b) (4)	

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:01
User entered 'No (N)'	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	11 Nov 2020 15:27:03
User entered '18 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 15:27:03
	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57
	(b) (4)	

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:05
User entered empty.	Stanley Dublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User entered empty.	System	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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.	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User entered empty.	System	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	11 Nov 2020 15:29:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 15:29:14
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	System	08 Sep 2020 17:29:05
User opened query 'Data is required. Please complete.' (Site from System).	Stanley Dublin (b) (4)	08 Sep 2020 17:29:05
User entered empty.	(b) (4)	08 Sep 2020 17:28:57
	System	08 Sep 2020 17:28:57
	Stanley Dublin (b) (4)	08 Sep 2020 17:28:57
	(b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:19
User entered '0'	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:20
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: 10 Jun 2021 08:07:29

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:22
User entered empty.	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:23
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: 10 Jun 2021 08:07:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:29:26
User entered empty.	Stanley Dublin (b) (4)	08 Sep 2020 17:28:57
	(b) (4)	

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:28
User entered '0'	Stanley Dublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:30
User entered '0'	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:31
User entered '0'	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:33
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:36
User entered 'None (NONE)'	Stanley Dublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:37
User entered 'l'	Stanley Doublin (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:40
User entered '0'	Stanley Dublin (b) (4) (b) (4)	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stanley Doublin (b) (4)	22 Sep 2020 12:43:11
Data Entry Error	(b) (4)	
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: 10 Jun 2021 08:07:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:29:43
User entered empty.	Stanley Dublin (b) (4)	08 Sep 2020 17:28:57
	(b) (4)	

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:45
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: 10 Jun 2021 08:07:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User entered '0'	System	08 Sep 2020 17:29:05

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51
User entered '0'	System	08 Sep 2020 17:28:57

US3552024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:07:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:21:51

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Vaccination site reactions, PT: Vaccination site pain, LLT: Vaccination site pain - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 20:27:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 20:27:33
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: Pain in extremity, LLT: Painful L arm - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 09:21:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 09:21:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
Data point term sent to Coder	System	08 Feb 2021 22:18:45
User entered 'left arm pain ipsilateral to vaccination arm'	Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '21 Jan 2021'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered '11:00' reason for change: Data Entry Error	System	08 Feb 2021 22:18:47
User opened query 'Data is required. Please provide.' (Site from System).	Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:47
User entered empty.	(b) (4)	
	System	08 Feb 2021 22:18:06
	Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06
	(b) (4)	

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered '21 Jan 2021 11:00'	System	08 Feb 2021 22:18:47
User entered empty.	System	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered empty.	System	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cassandra Zehenny (b) (4) (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'Related (RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered '0'	System	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered '0'	System	08 Feb 2021 22:18:06

US3552024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:07:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:07:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:14:59
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	14 Aug 2020 12:47:59
	(b) (4)	

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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)	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.	Coder Import (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

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:29

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	14 Aug 2020 12:51:21
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 12:51:21
Data point term sent to Coder	System	14 Aug 2020 12:50:21
User entered 'losartan'	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: 10 Jun 2021 08:07:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (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: 10 Jun 2021 08:07:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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 Doublin (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: 10 Jun 2021 08:07:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '100'	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: 10 Jun 2021 08:07:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'mg (mg)'	Stanley Doublin (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: 10 Jun 2021 08:07:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (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: 10 Jun 2021 08:07:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	28 Oct 2020 16:20:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Oct 2020 16:20:19
	Stanley Doublin (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: 10 Jun 2021 08:07:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (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: 10 Jun 2021 08:07:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	28 Oct 2020 16:20:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 16:20:19
	Stanley Doublin (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: 10 Jun 2021 08:07:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (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: 10 Jun 2021 08:07:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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.'	Stanley Doublin (b) (4)	14 Aug 2020 12:49:55
answered with 'data is correct' (Site from System).	(b) (4)	
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
	(b) (4)	

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '0'	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: 10 Jun 2021 08:07:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Yes (Y)'	Stanley Doublin (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: 10 Jun 2021 08:07:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	28 Oct 2020 16:20:19
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
	Stanley Doublin (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: 10 Jun 2021 08:07:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	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: 10 Jun 2021 08:07:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered 'I'	System	14 Aug 2020 12:49:47

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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	System	14 Aug 2020 13:40:50
Coding entries removed.	Joan Siegner (b) (4) (b) (4)	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	System	14 Aug 2020 12:51:22
User entered 'amlodipine'	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: 10 Jun 2021 08:07:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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 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: 10 Jun 2021 08:07:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:07:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:07:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:07:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:07:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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.'	Stanley Doublin (b) (4) (b) (4)	14 Aug 2020 12:51:20
answered with 'data is correct' (Site from System).		
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) (b) (4)	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User entered 'I'	System	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
User entered 'I'	System	14 Aug 2020 12:51:13

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:29
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: 10 Jun 2021 08:07:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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)	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)	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)	06 Oct 2020 12:57:05
User entered 'TIMOLOL MALEATE 0.5%' reason for change: Data Entry Error	Stanley Doublin (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)	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)	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)	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)	15 Aug 2020 08:50:12

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:29

[Name of Medication](#)

Audit	User	Time (GMT)
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 Dublin (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: 10 Jun 2021 08:07:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (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: 10 Jun 2021 08:07:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	28 Oct 2020 16:20:19
User entered 'glaucoma'	(b) (4), (b) (6)	28 Oct 2020 16:20:19
	Stanley Doublin (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: 10 Jun 2021 08:07:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'l'	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: 10 Jun 2021 08:07:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Other (OTHER)'	Stanley Doublin (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: 10 Jun 2021 08:07:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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).		07 Oct 2020 12:30:57
Query ' 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).	Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:57:16
User entered 'DROP' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:57:05
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).	(b) (4), (b) (6)	05 Oct 2020 13:29:42
User entered 'drop 0.5%'	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: 10 Jun 2021 08:07:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'twice daily (BID)'	Stanley Doublin (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: 10 Jun 2021 08:07:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (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: 10 Jun 2021 08:07:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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 Dublin (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

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:29

[Route of administration](#)

Audit	User	Time (GMT)
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) (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
User entered 'Intraocular (INTRAOCULAR)' reason for change: Per Query Resolution	Heather Douds (b) (4) (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) (b) (4)	14 Aug 2020 12:57:18

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'both eyes'	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: 10 Jun 2021 08:07:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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).		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.'	Stanley Doublin (b) (4)	14 Aug 2020 12:57:26
answered with 'data is correct' (Site from System).	(b) (4)	
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
	(b) (4)	

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '0'	Stanley Doublin (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: 10 Jun 2021 08:07:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Yes (Y)'	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: 10 Jun 2021 08:07:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (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: 10 Jun 2021 08:07:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	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: 10 Jun 2021 08:07:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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)	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)	14 Aug 2020 13:42:23
Data point term sent to Coder	System	14 Aug 2020 13:41:51
Coding entries removed.	Joan Siegner (b) (4)	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)	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)	14 Aug 2020 12:59:20
Data point term sent to Coder	System	14 Aug 2020 12:58:34
User entered 'amlodipine'	Stanley Doublin (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	Stanley Doublin (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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 Doublin (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '10'	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: 10 Jun 2021 08:07:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'mg (mg)'	Stanley Doublin (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Doublin (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	28 Oct 2020 16:20:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Oct 2020 16:20:19
	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: 10 Jun 2021 08:07:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	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: 10 Jun 2021 08:07:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:07:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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).		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.'	Stanley Dublin (b) (4)	14 Aug 2020 12:58:35
answered with 'data is correct' (Site from System).	(b) (4)	
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 12:58:27
User entered 'un Jul 2020'	Stanley Dublin (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: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered '0'	Stanley Doublin (b) (4)	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Yes (Y)'	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: 10 Jun 2021 08:07:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:07:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	28 Oct 2020 16:20:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:20:19
	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: 10 Jun 2021 08:07:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered 'I'	System	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User entered 'I'	System	14 Aug 2020 12:58:27

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
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: 10 Jun 2021 08:07:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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) (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) (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) (b) (4)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Yes (Y)'	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: 10 Jun 2021 08:07:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'Influenza Prevention'	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: 10 Jun 2021 08:07:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'l'	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: 10 Jun 2021 08:07:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'once (ONCE)'	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: 10 Jun 2021 08:07:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
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
	(b) (4)	

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	11 Nov 2020 15:31:20
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 15:31:20
	Stanley Doublin (b) (4)	09 Nov 2020 15:52:38
	(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
	(b) (4)	09 Nov 2020 15:52:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
	(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)	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	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: 10 Jun 2021 08:07:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	11 Nov 2020 15:31:21
DataPoint Un-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	(b) (4)	09 Nov 2020 15:52:38
DataPoint Verified.	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
	(b) (4)	

US3552024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:20:19
User entered 'No (N)'	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: 10 Jun 2021 08:07:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
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: 10 Jun 2021 08:07:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
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: 10 Jun 2021 08:07:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:13:34
User entered empty.	System	12 Oct 2020 15:33:48

US3552024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:07:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	18 Feb 2021 15:54:48

US3552024

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:07:29

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:31
User entered '14 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 18:45:36

US3552024

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:07:29

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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).		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).		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).		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: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
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: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:07:29

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	20 Apr 2021 19:38:39
User entered '20 Apr 2021'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 16:33:54

US3552024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:07:29

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	20 Apr 2021 19:38:39
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 16:33:54

US3552024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	20 Apr 2021 19:38:39
User entered 'subject will be in Ethiopia until May 2022 and unable to complete safety calls and visits during that time'	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 16:33:54

US3552024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:07:29

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	20 Apr 2021 19:38:39
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 16:33:54

US3552024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:07:29

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	20 Apr 2021 19:38:39
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 16:33:54

US3552024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:07:29

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	20 Apr 2021 19:38:39
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 16:33:54

US3552024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:07:29

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	20 Apr 2021 19:38:39
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Apr 2021 16:33:54

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '6'	(b) (4)	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: 10 Jun 2021 08:07:29

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:07:29

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:07:29

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.		15 Sep 2020 18:41:07
Amendment Manager: User entered 'MO'		14 Sep 2020 21:51:25

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	09 Nov 2020 17:30:51
User entered '63104'	(b) (4), (b) (6)	09 Nov 2020 16:37:08
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:07:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '6'	(b) (4)	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: 10 Jun 2021 08:07:29

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:32:41
User entered '04/Sep/2020 13:14'	(b) (4), (b) (6)	04 Sep 2020 17:14:49
	System	04 Sep 2020 17:14:49

US3552024

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

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 16:38:00
User entered 'I'		04 Sep 2020 17:14:49

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:07:29

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '6'	(b) (4)	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: 10 Jun 2021 08:07:29

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:32:41
User entered '09/Sep/2020 12:38'	(b) (4), (b) (6)	09 Sep 2020 16:38:15
	System	09 Sep 2020 16:38:15

US3552024

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

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 10:18:52
User entered 'I'		09 Sep 2020 16:38:15

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '6'	(b) (4)	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: 10 Jun 2021 08:07:29

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 18:41:07
User entered 'I'		13 Sep 2020 10:19:03

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	09 Nov 2020 17:30:49
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '6'	(b) (4)	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: 10 Jun 2021 08:07:29

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 12:45:38
User entered 'I'		15 Sep 2020 18:41:21

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	09 Nov 2020 17:30:48
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:37:08

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	09 Nov 2020 17:30:51
User entered '63104'	(b) (4), (b) (6)	09 Nov 2020 16:37:08
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '6'	(b) (4)	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: 10 Jun 2021 08:07:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:32:41
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:21:22
User entered 'l'		23 Sep 2020 12:45:54

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 20:32:41
Reviewed for Safety.		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: 10 Jun 2021 08:07:29

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	09 Nov 2020 17:30:49
User entered '1100 S. Grand Blvd'	(b) (4), (b) (6)	09 Nov 2020 16:37:08
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:07:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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

US3552024

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:29

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
User entered '6'	(b) (4)	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: 10 Jun 2021 08:07:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
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: 10 Jun 2021 08:07:29

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:27:53
DataPoint Verified.	(b) (4)	12 Oct 2020 20:32:41
User entered 'l'	(b) (4), (b) (6)	01 Oct 2020 12:21:30