

US3572170 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3572170

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 04:40:31

Generated On: 10 Jun 2021 08:17:31

[Participant ID](#)

US3572170

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 03:36:47

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Mar 2021 03:36:43

Generated On: 10 Jun 2021 08:17:31

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Mar 2021 03:36:43

Generated On: 10 Jun 2021 08:17:31

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Mar 2021 03:36:43

Generated On: 10 Jun 2021 08:17:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Mar 2021 03:36:46

Generated On: 10 Jun 2021 08:17:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Mar 2021 03:36:46

Generated On: 10 Jun 2021 08:17:31

Condition	DIABETES TYPE II
Start date (dd MMM yyyy)	01 JAN 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Mar 2021 03:36:46

Generated On: 10 Jun 2021 08:17:31

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 JAN 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Mar 2021 03:36:46

Generated On: 10 Jun 2021 08:17:31

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	01 JAN 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Mar 2021 03:36:46

Generated On: 10 Jun 2021 08:17:31

Condition	PAROXYSMAL ATRIAL FIBRILLATION (AFIB)
Start date (dd MMM yyyy)	01 JAN 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Mar 2021 03:36:46

Generated On: 10 Jun 2021 08:17:31

Condition	GLAUCOMA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Mar 2021 03:36:47

Generated On: 10 Jun 2021 08:17:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:00
Height (xxx.x)	71 in
Weight (xxx.x)	195 lb
BMI (xxx.x)	27.25385 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 19:14:35

Generated On: 10 Jun 2021 08:17:31

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.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:36:46

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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 NONE; PT IS RETIRED.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:36:46

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 190523

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	08:09 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 08:09
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	08:57 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 08:57
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 19:14:35

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 8:27 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 8:27

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	08:11 (24 HR)
Collection date and time (derived)	10 SEP 2020 08:11

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:20	10 SEP 2020 08:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

97.6 °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

10 SEP 2020 09:04

PC Open Date & Time

10 SEP 2020 08:47

PC Close Date & Time

10 SEP 2020 11:17

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 97.6 °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	10 SEP 2020 20:31
PC Open Date & Time	10 SEP 2020 12:12
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

97.5 °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

11 SEP 2020 12:03

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

97.9 °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

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

97.5 °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 SEP 2020 12:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

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

14 SEP 2020 12:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

97.5 °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 SEP 2020 12:00

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

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

16 SEP 2020 12:02

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

10 SEP 2020 09:05

PC Open Date & Time

10 SEP 2020 08:47

PC Close Date & Time

10 SEP 2020 11:17

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

10 SEP 2020 20:31

PC Open Date & Time

10 SEP 2020 12:12

PC Close Date & Time

11 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

11 SEP 2020 12:03

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

12 SEP 2020 12:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

13 SEP 2020 12:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

14 SEP 2020 12:04

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

15 SEP 2020 12:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

16 SEP 2020 12:03

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 09:06
PC Open Date & Time	10 SEP 2020 08:47
PC Close Date & Time	10 SEP 2020 11:17

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 20:32
PC Open Date & Time	10 SEP 2020 12:12
PC Close Date & Time	11 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 12:04
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:03
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:04
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

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EAB) (1725)

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 12:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

56 of 2179

EAB) (1725)

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 12:03
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3572170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 OCT 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 09:50
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 OCT 2020
Time of assessment (00:00-23:59)	10:57 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 10:57
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3572170

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 OCT 2020

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

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

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) 8 OCT 2020

What was the treatment time? (00:00-23:59) 10:27 (24 HR)

Treatment Date and Time (derived) 8 OCT 2020 10:27

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

US3572170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 OCT 2020
Collection time (00:00-23:59)	10:00 (24 HR)
Collection date and time (derived)	08 OCT 2020 10:00

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)			08 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:56	08 OCT 2020 09:56
Nasopharyngeal Swab 2	No		

US3572170

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

97.9 °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

08 OCT 2020 10:55

PC Open Date & Time

08 OCT 2020 10:47

PC Close Date & Time

08 OCT 2020 13:17

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

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	08 OCT 2020 17:36
PC Open Date & Time	08 OCT 2020 14:12
PC Close Date & Time	09 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

97.7 °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

10 OCT 2020 06:10

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

98.0 °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

10 OCT 2020 16:28

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

97.7 °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

11 OCT 2020 20:51

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

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

12 OCT 2020 16:17

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

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

14 OCT 2020 08:08

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

97.1 °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 OCT 2020 12:16

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

08 OCT 2020 10:56

PC Open Date & Time

08 OCT 2020 10:47

PC Close Date & Time

08 OCT 2020 13:17

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

08 OCT 2020 17:36

PC Open Date & Time

08 OCT 2020 14:12

PC Close Date & Time

09 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

10 OCT 2020 06:10

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

10 OCT 2020 16:28

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

11 OCT 2020 20:52

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

12 OCT 2020 16:17

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

14 OCT 2020 08:08

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

14 OCT 2020 12:16

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 10:56
PC Open Date & Time	08 OCT 2020 10:47
PC Close Date & Time	08 OCT 2020 13:17

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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 ☐

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 17:38
PC Open Date & Time	08 OCT 2020 14:12
PC Close Date & Time	09 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

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 ☒

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 06:11
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

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 ☒

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EAB) (1725)

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 16:29
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

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 ☒

PRODUCTION RELEASE (v12.003

96 of 2179

EAB) (1725)

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 20:52
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

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EAB) (1725)

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 16:18
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

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EAB) (1725)

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 08:08
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

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EAB) (1725)

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 12:16
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3572170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:01

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 NOV 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 08:15
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572170

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3572170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 NOV 2020
Collection time (00:00-23:59)	08:20 (24 HR)
Collection date and time (derived)	6 NOV 2020 08:20

US3572170

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:02

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

14 NOV 2020 09:01:21

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

17 NOV 2020 06:52:21

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 06:10:47
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 05:48:10
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 08:12:47
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 07:21:28
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

19 DEC 2020 06:42:17

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

26 DEC 2020 06:36:32

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

02 JAN 2021 07:09:11

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 06:20:37
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

16 JAN 2021 08:39:00

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

23 JAN 2021 06:21:37

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

30 JAN 2021 06:24:35

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

06 FEB 2021 04:55:41

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

13 FEB 2021 06:52:29

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

20 FEB 2021 08:54:46

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

27 FEB 2021 08:35:09

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 08:05:32
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 05:28:51

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 MAR 2021 00:28:39

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 MAR 2021 09:22:52
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <input type="radio"/> Yes <input checked="" type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 APR 2021 12:21:32
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

10 APR 2021 10:22:43

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <input type="radio"/> Yes <input checked="" type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 APR 2021 05:15:27
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <input type="radio"/> Yes <input checked="" type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 APR 2021 07:46:28
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

01 MAY 2021 09:21:20

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 572
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

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15 JUN 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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06 JUL 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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13 JUL 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

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06 AUG 2022 00:01

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10 AUG 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

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13 AUG 2022 00:01

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17 AUG 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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27 AUG 2022 00:01

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31 AUG 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

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07 SEP 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

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14 SEP 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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21 SEP 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

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24 SEP 2022 00:01

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28 SEP 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

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01 OCT 2022 00:01

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05 OCT 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

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08 OCT 2022 00:01

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12 OCT 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

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15 OCT 2022 00:01

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19 OCT 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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02 NOV 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3572170

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:17:31

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		04 MAR 2021 13:17:14

US3572170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:17:20

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:17:20

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 19:14:35

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 19:14:35

Generated On: 10 Jun 2021 08:17:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 APR 2021
Time of assessment (00:00-23:59)	14:46 (24 HR)
Vital Signs Date and Time (derived)	6 APR 2021 14:46
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572170

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 19:14:35

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 APR 2021

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

US3572170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 19:14:35

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 APR 2021
Collection time (00:00-23:59)	13:30 (24 HR)
Collection date and time (derived)	6 APR 2021 13:30

US3572170

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:14:35

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572170

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	21 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3572170

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

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 <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	21 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3572170

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

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

US3572170

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	17:00 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 17:00
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3572170

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	20:25 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 20:25
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	49 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)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3572170

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

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

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.

US3572170

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

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

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) 19:55 (24 HR)

Treatment Date and Time (derived) 21 JAN 2021 19:55

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

US3572170

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

17:56 (24 HR)

Collection date and time (derived)

21 JAN 2021 17:56

US3572170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	17:54
Collection Date and Time (derived)	21 JAN 2021 17:54

US3572170

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

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3572170

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Apr 2021 05:40:33

Generated On: 10 Jun 2021 08:17:31

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	17:30 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 17:30
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Apr 2021 05:40:33

Generated On: 10 Jun 2021 08:17:31

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	18:05 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 18:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3572170

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3572170

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

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) 19 FEB 2021

What was the treatment time? (00:00-23:59) 18:05 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 18:05

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

US3572170

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572170

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:40:50

Generated On: 10 Jun 2021 08:17:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572170

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3572170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

US3572170

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

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.

US3572170

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3572170

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 Apr 2021 04:40:31

Generated On: 10 Jun 2021 08:17:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 15:47:41

Generated On: 10 Jun 2021 08:17:31

AEID	
Adverse event	S/P FALL
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SUBJECT CONTINUES TO HAVE CHRONIC NECK PAIN.
Narrative	

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Folder: Adverse Events

Form: Adverse Events (1)

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Generated On: 10 Jun 2021 08:17:31

SUBJECT STATES HE SLIPPED
ON SOME ICE ON 2/17/2021 AND
INJURED HIS NECK. HE HAS A
HISTORY OF BACK INJURY
FROM SEVERAL YEARS AGO
AND HE FEELS SINCE HIS FALL,
HE IS EXPERIENCING CHRONIC
PAIN IN CERVICAL SPINE
AREA. HE IS NOT TAKING ANY
NEW MEDICATIONS TO TREAT
PAIN.

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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 15:47:41

Generated On: 10 Jun 2021 08:17:31

AEID

Adverse event

NECK INJURY DUE TO FALL

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)

17 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 MAR 2021

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 15:47:41

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 15:47:41

Generated On: 10 Jun 2021 08:17:31

AEID	USA-US091-2021-MRNA-1273-P30 1000018
Adverse event	GASTROESOPHAGEAL REFLUX DISEASE
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	29 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input checked="" type="checkbox"/>
Is the adverse event serious?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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)	12 APR 2021
Hospital Discharge Date (dd MMM yyyy)	14 APR 2021
Admitted to ICU?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 15:47:41

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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 <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PI REPORTED TODAY (4/13) THAT SUBJECT HAD AN MI AND WAS HOSPITALIZED AND UNDERWENT ANGIOPLASTY. HE IS CURRENTLY IN THE HOSPITAL; MEDICAL RECORDS HAVE BEEN REQUESTED.

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 15:47:41

Generated On: 10 Jun 2021 08:17:31

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 15:47:41

Generated On: 10 Jun 2021 08:17:31

AEID	USA-US091-2021-MRNA-1273-P30 1000018
Adverse event	NSTEMI
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10 APR 2021
Hospital Discharge Date (dd MMM yyyy)	14 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 15:47:41

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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 <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 15:47:41

Generated On: 10 Jun 2021 08:17:31

SUBJECT HAVING GRADUAL
ONSET OF CHEST PAIN
DESCRIBED AS CHEST
TIGHTNESS 1 HR PRIOR TO
ADMISSION. NO ASSOCIATED
SYMPTOMS SUCH AS NAUSEA,
VOMITING OR DIAPHORESIS.
SUBJECT HAD BOUTS OF
SHORTNESS OF BREATH ON
EXERTION. ECG REVEALED
NONSPECIFIC ST CHANGES, IN
JANUARY 2020 THE SUBJECT
UNDERWENT A STRESS TEST
WHICH REVEALED
MYOCARDIAL PERFUSION BE
NORMAL WITH NO EVIDENCE
OF REVERSIBLE ISCHEMIA OR
FIXED THE LEFT VENTRICULAR
DIASTOLIC SYSTOLIC
FUNCTION WAS NORMAL
WITHOUT EVIDENCE OF
REGIONAL WALL MOTION, THE
SUBJECT HAS A HISTORY OF
ATRIAL FIBRILLATION
PROXIMAL TO WHICH
THE SUBJECT BEEN ON
FLECAINIDE.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 04:40:32

Generated On: 10 Jun 2021 08:17:31

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication GLIMEPIRIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS II

Dose per administration 4

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication LEVEMIR

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS II

Dose per administration 6

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNITS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication PROPRANOLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 40

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication COMBIGAN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication LATANOPROST

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC ROUTE	
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication POTASSIUM CITRATE
EXTENDED RELEASE
(SUPPLEMENT)

Prophylaxis Yes ☒
No ☐

Indication RENAL CALCULI PREVENTION
SUPPLEMENT

Dose per administration 540

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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)

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US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication AMIODARONE

Prophylaxis Yes ☒
No ☐

Indication ANTIARRHYTHMIC

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

Name of Medication PLAVIX

Prophylaxis Yes ☒
No ☐

Indication BLOOD THINNER

Dose per administration 75

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 22:01:23

Generated On: 10 Jun 2021 08:17:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3572170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 22:40:36

Generated On: 10 Jun 2021 08:17:31

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3572170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 22:40:36

Generated On: 10 Jun 2021 08:17:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 APR 2021	CARDIAC CATHETERIZATION	Adverse Event	

US3572170

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:17:31

Date of dosing discontinuation (dd MMM yyyy)

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

US3572170

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:17:31

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US091-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US091-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/APR/2021 13:02
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

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US091-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	27/APR/2021 09:55
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

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US091-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/APR/2021 10:09
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

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US091-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/APR/2021 06:18
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

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 16:37:41

Generated On: 10 Jun 2021 08:17:31

SAEID	USA-US091-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/APR/2021 08:14
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

Audit

US3572170 (Prod: Laguna Clinical Research Associates)

US3572170

Form: Participant Creation

Generated On: 10 Jun 2021 08:17:31

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:18:43
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'US3572170'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:39:43

US3572170

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:41
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:24

US3572170

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:41
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:39:44

US3572170

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[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 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:41
User entered 'Clinic (Clinic)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:24

US3572170

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'SCRN'	System	02 Sep 2020 21:44:24

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:39:45

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered '71'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'YEARS'	System	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered '71'	System	02 Sep 2020 21:45:09

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered 'Male (M)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered 'l'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Sep 2020 19:37:59
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:37:59
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:44:50

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Sep 2020 19:38:06
User entered '2 Sep 2020'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:45:09

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'Sep 2020'	System	02 Sep 2020 21:45:09

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered '2020'	System	02 Sep 2020 21:45:09

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:38:06
User entered 'Amendment 3 (3)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:45:09

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Sep 2020 19:38:06
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:45:09

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Sep 2020 19:38:06
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:45:09

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:38:06
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:45:09

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Sep 2020 19:38:06
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:45:09

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 19:38:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:39:44

US3572170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'l'	System	02 Sep 2020 21:45:28

US3572170

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:16:45
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:45:28

US3572170

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:17:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
User closed query 'Per source, glaucoma is noted (start 2018). Please review and reconcile med hx list.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 22:15:25
Query 'Per source, glaucoma is noted (start 2018). Please review and reconcile med hx list.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 23:36:47
User opened query 'Per source, glaucoma is noted (start 2018). Please review and reconcile med hx list.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:35:59
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 19:53:01
User entered 'Yes (Y)'	Alisha Lutat (b) (4)	02 Sep 2020 21:46:10

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 22:15:30
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:12:03
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 18:17:38
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:48:51
Data point term sent to Coder	System	02 Sep 2020 21:48:13
User entered 'Diabetes Type II'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '01 Jan 2000'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 22:15:30
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'Jan 2000'	System	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered '2000'	System	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	02 Sep 2020 21:47:19

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 22:15:30
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:12:09
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 18:18:00
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)	02 Sep 2020 21:48:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:48:50
Data point term sent to Coder	System	02 Sep 2020 21:48:15
User entered 'Hypertension'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '01 Jan 1970'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'Jan 1970'	System	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered '1970'	System	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	02 Sep 2020 21:48:15

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:51:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:51:33
Data point term sent to Coder	System	02 Sep 2020 21:49:18
User entered 'Hyperlipidemia'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '01 Jan 1970'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 22:15:30
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'Jan 1970'	System	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered '1970'	System	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	02 Sep 2020 21:48:50

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 22:15:30
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:12:32
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 18:18:16
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:09:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:09:49
Data point term sent to Coder	System	02 Sep 2020 21:51:22
User entered 'paroxysmal atrial fibrillation (AFIB)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '01 Jan 1980'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 22:15:30
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 22:15:30
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'Jan 1980'	System	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered '1980'	System	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	02 Sep 2020 21:50:25

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:30
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)	16 Dec 2020 23:38:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 23:38:05
Data point term sent to Coder	System	16 Dec 2020 23:37:14
User entered 'GLAUCOMA'	(b) (4), (b) (6)	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered 'UN UNK 2018'	(b) (4), (b) (6)	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:30
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'Jan 2018'	System	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered '2018'	System	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered empty.	System	16 Dec 2020 23:36:37

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:22:11
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:00:06

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:22:13
User entered '2 Sep 2020'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:00:06

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:22:15
User entered '12:00'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:00:06

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered '2 Sep 2020 12:00'	System	02 Sep 2020 22:00:06

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:22:16
User entered '71' in	Alisha Lutat (b) (4)	02 Sep 2020 22:00:06
DataPoint set to visible.	(b) (4) System	02 Sep 2020 21:45:28

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:22:18
User entered '195' lb	Alisha Lutat (b) (4)	02 Sep 2020 22:00:06
DataPoint set to visible.	(b) (4) System	02 Sep 2020 21:45:28

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered '27.25385'	System	02 Sep 2020 22:00:06
DataPoint set to visible.	System	02 Sep 2020 21:45:28

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'kg/m2'	System	02 Sep 2020 22:00:06
DataPoint set to visible.	System	02 Sep 2020 21:45:28

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:41
User closed query 'Per source, temp and BP measurements are not noted as collected on 02Sep/not in source. Please review and confirm if temp and the rest of this page should be updated to not done?' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 22:15:39
Query 'Per source, temp and BP measurements are not noted as collected on 02Sep/not in source. Please review and confirm if temp and the rest of this page should be updated to not done?' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 23:34:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:34:26
User opened query 'Per source, temp and BP measurements are not noted as collected on 02Sep/not in source. Please review and confirm if temp and the rest of this page should be updated to not done?' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:21:40
User entered '98.7' F	Alisha Lutat (b) (4)	02 Sep 2020 22:00:06
	(b) (4)	

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:34:26
User entered 'Other (Other)'	Alisha Lutat (b) (4)	02 Sep 2020 22:00:06
	(b) (4)	

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:15:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:34:26
User entered 'Temporal'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:00:06

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:41
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	16 Dec 2020 23:34:26
change Data Entry Error		
User entered '67'	Alisha Lutat (b) (4)	02 Sep 2020 22:00:06
	(b) (4)	

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'bpm'	System	02 Sep 2020 22:00:06

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:41
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	16 Dec 2020 23:34:26
change Data Entry Error		
User entered '18'	Alisha Lutat (b) (4)	02 Sep 2020 22:00:06
	(b) (4)	

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'breaths/min'	System	02 Sep 2020 22:00:06

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:41
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	16 Dec 2020 23:34:26
change Data Entry Error		
User entered '132'	Alisha Lutat (b) (4)	02 Sep 2020 22:00:06
	(b) (4)	

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'mmHg'	System	02 Sep 2020 22:00:06

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:15:41
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	16 Dec 2020 23:34:26
change Data Entry Error		
User entered '70'	Alisha Lutat (b) (4)	02 Sep 2020 22:00:06
	(b) (4)	

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User entered 'mmHg'	System	02 Sep 2020 22:00:06

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22

US3572170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22

US3572170

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:26
User closed query 'A PE form conducted on 10 Sep 2020. Please clarify if PE is for VID1 or Screening. Amend this form as needed.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:52:23
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Query 'A PE form conducted on 10 Sep 2020. Please clarify if PE is for VID1 or Screening. Amend this form as needed.' answered with 'PE was conducted on 10SEP20 for VID1. Screening PE eCRF updated accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:10:17
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 21:09:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:09:32
User opened query 'A PE form conducted on 10 Sep 2020. Please clarify if PE is for VID1 or Screening. Amend this form as needed.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:55:48
Query 'EMR notes that PE was conducted at a later visit, but no PE chart is provided to confirm. Please upload PE for 10 Sep 2020.' canceled (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:54:30
User opened query 'EMR notes that PE was conducted at a later visit, but no PE chart is provided to confirm. Please upload PE for 10 Sep 2020.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:47:05
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 23:35:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:35:01
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 20:07:39
User entered 'No (N)'	Brett Potthoff (b) (4)	10 Sep 2020 13:15:44

US3572170

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:26
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Signature has been broken.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 21:09:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:09:32
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	16 Dec 2020 23:35:01
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:35:01
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 20:07:39
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'None; pt is retired.'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
User entered '0'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered '0'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered 'l'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
User entered '0'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:22
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:36:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:50:27
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 22:04:52

US3572170

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 07:19:08
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:25:51
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:30:55
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:11:28

US3572170

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:25:51
User entered '10 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:11:28

US3572170

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[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 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:25:51
User entered 'Clinic (Clinic)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:11:28

US3572170

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'VISIT1'	System	10 Sep 2020 13:11:28

US3572170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:28:31
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:09:32

US3572170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:28:31
User entered '190523'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:09:32

US3572170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:28:31
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:09:32

US3572170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:28:31
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:19:41

US3572170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:28:31
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:19:41

US3572170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:28:31
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:19:41

US3572170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:03
User closed query 'Per CCGs, as subject meets this risk by age this should be no. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 18:43:01
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
Query 'Per CCGs, as subject meets this risk by age this should be no. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 18:17:41
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 18:17:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 18:17:33
User opened query 'Per CCGs, as subject meets this risk by age this should be no. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 22:16:23
User closed query 'Per protocol, subject meets risk by age. Please confirm this answer should be changed to no.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 22:16:23
Query 'Per protocol, subject meets risk by age. Please confirm this answer should be changed to no.' answered with 'As per subject source...subject has history of Diabetes type II since 01JAN2020' (Site from CRA).	(b) (4), (b) (6)	30 Nov 2020 20:21:43
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:28:31
User opened query 'Per protocol, subject meets risk by age. Please confirm this answer should be changed to no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:28:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 20:19:41

US3572170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:28:31
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:19:41

US3572170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:28:31
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:19:41
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:56:27
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:56:26

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:30:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:30:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '10 Sep 2020'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '08:09'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered '10 Sep 2020 08:09'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '97.5' F	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered 'Other (Other)'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered 'TEMPORAL'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '53'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'bpm'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '18'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'breaths/min'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '131'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'mmHg'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '75'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'mmHg'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:30:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:30:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '10 Sep 2020'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '08:57'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered '10 Sep 2020 08:57'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '97.5' F	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered 'Other (Other)'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered 'TEMPORAL'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '51'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'bpm'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '18'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'breaths/min'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '128'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'mmHg'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:30:07
User entered '73'	(b) (4), (b) (6)	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'mmHg'	System	29 Oct 2020 20:21:55

US3572170

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 02:45:14
User closed query 'A PE form for 10 Sep 2020 was found in the EMR. Please confirm if accurate for V1 and update this page as required.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Milton Haber (b) (4)	20 Apr 2021 02:44:52 15 Apr 2021 19:14:36
Query 'A PE form for 10 Sep 2020 was found in the EMR. Please confirm if accurate for V1 and update this page as required.' answered with 'PE was conducted on 10SEP20 for V1D1. This V1D1 PE eCRF has been updated accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:12:12
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 21:11:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:11:24
User opened query 'A PE form for 10 Sep 2020 was found in the EMR. Please confirm if accurate for V1 and update this page as required.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Milton Haber (b) (4)	12 Apr 2021 20:54:10 21 Mar 2021 00:15:02
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 23:33:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:33:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 20:13:22
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:16:26

US3572170

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 02:45:14
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Signature has been broken.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 21:11:24
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:11:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	16 Dec 2020 23:33:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:33:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 20:13:22
User entered '10 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:16:26

US3572170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:12:01
User closed query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 10SEP2020, however the same is missing in EDC. Please add or clarify' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:23:47
Query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 10SEP2020, however the same is missing in EDC. Please add or clarify' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 23:38:03
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 23:37:59
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:30:41
User opened query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 10SEP2020, however the same is missing in EDC. Please add or clarify' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 14:30:10
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:23:20
User entered 'Yes (Y)'	Brett Potthoff (b) (4)	10 Sep 2020 13:35:39

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:30:41
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:35:39

US3572170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:41
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:35:39

US3572170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 13:35:39

US3572170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:30:41
User entered '10 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:35:39

US3572170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:30:41
User entered '8:27'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:35:39

US3572170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered '10 Sep 2020 8:27'	System	10 Sep 2020 13:35:39

US3572170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:30:41
User entered 'Left Arm (LEFT ARM)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 13:35:39

US3572170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:30:41
User entered 'ONCE'	System	10 Sep 2020 13:35:39

US3572170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 13:35:39

US3572170

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 20:17:50

US3572170

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:12
User entered '10 Sep 2020'	(b) (4), (b) (6)	29 Oct 2020 20:17:50

US3572170

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:31:12
User entered '08:11'	(b) (4), (b) (6)	29 Oct 2020 20:17:50

US3572170

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered '10 Sep 2020 08:11'	System	29 Oct 2020 20:17:50

US3572170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:17:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:20
User entered '10 Sep 2020'	(b) (4), (b) (6)	29 Oct 2020 20:18:15

US3572170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Oct 2020 20:18:15

US3572170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 20:18:15

US3572170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:20
User entered '08:20'	(b) (4), (b) (6)	29 Oct 2020 20:18:15

US3572170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered '10 Sep 2020 08:20'	System	29 Oct 2020 20:18:15

US3572170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Oct 2020 20:18:15

US3572170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:20
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:19:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 20:19:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:19:18
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:18:15
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:18:15

US3572170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:20
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:18:15

US3572170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered empty.	System	29 Oct 2020 20:18:15

US3572170

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:31:31
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 13:42:37

US3572170

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:34
User entered 'I'	System	18 Sep 2020 13:42:37

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:04:39', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'bbf2ed54-d234-4b79-964e-6709938be154'	System	10 Sep 2020 14:04:10
User entered 'Yes (Y)'	System	10 Sep 2020 14:04:10

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:04:46', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'bbf2ed54-d234-4b79-964e-6709938be154'	System	10 Sep 2020 14:04:10
User entered '97.6'	System	10 Sep 2020 14:04:10

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:04:51', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'bbf2ed54-d234-4b79-964e-6709938be154'	System	10 Sep 2020 14:04:10
User entered 'No (N)'	System	10 Sep 2020 14:04:10

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:04:56', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'bbf2ed54-d234-4b79-964e-6709938be154'	System	10 Sep 2020 14:04:10
User entered '10 Sep 2020 09:04'	System	10 Sep 2020 14:04:10

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Sep 2020 08:47'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Sep 2020 11:17'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:30:59', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '21e832d4-b90c-4e95-9ded-71dafebc5a21'	System	11 Sep 2020 01:30:41
User entered 'Yes (Y)'	System	11 Sep 2020 01:30:41

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:31:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '21e832d4-b90c-4e95-9ded-71dafebc5a21'	System	11 Sep 2020 01:30:41
User entered '97.6'	System	11 Sep 2020 01:30:41

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:31:14', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '21e832d4-b90c-4e95-9ded-71dafebc5a21'	System	11 Sep 2020 01:30:41
User entered 'No (N)'	System	11 Sep 2020 01:30:41

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:31:25', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '21e832d4-b90c-4e95-9ded-71dafebc5a21'	System	11 Sep 2020 01:30:41
User entered '10 Sep 2020 20:31'	System	11 Sep 2020 01:30:41

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Sep 2020 12:12'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 2'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:02:45', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '65197696-68ea-4ed5-8562-28d2a59d3683'	System	11 Sep 2020 17:02:51
User entered 'Yes (Y)'	System	11 Sep 2020 17:02:51

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:02:51', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '65197696-68ea-4ed5-8562-28d2a59d3683' User entered '97.5'	System	11 Sep 2020 17:02:51
	System	11 Sep 2020 17:02:51

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:02:56', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '65197696-68ea-4ed5-8562-28d2a59d3683'	System	11 Sep 2020 17:02:51
User entered 'No (N)'	System	11 Sep 2020 17:02:51

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '65197696-68ea-4ed5-8562-28d2a59d3683'	System	11 Sep 2020 17:02:51
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 17:02:51

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 3'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:01:25', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '43e8a2d8-a158-445d-a852-2bf078d57179'	System	12 Sep 2020 17:01:20
User entered 'Yes (Y)'	System	12 Sep 2020 17:01:20

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:01:35', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '43e8a2d8-a158-445d-a852-2bf078d57179'	System	12 Sep 2020 17:01:20
User entered '97.9'	System	12 Sep 2020 17:01:20

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:01:39', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '43e8a2d8-a158-445d-a852-2bf078d57179'	System	12 Sep 2020 17:01:20
User entered 'No (N)'	System	12 Sep 2020 17:01:20

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:01:44', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '43e8a2d8-a158-445d-a852-2bf078d57179'	System	12 Sep 2020 17:01:20
User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:01:20

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 4'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:02', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'bd2c11b2-954e-47d4-98a4-b8dd27e30533'	System	13 Sep 2020 17:01:56
User entered 'Yes (Y)'	System	13 Sep 2020 17:01:56

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'bd2c11b2-954e-47d4-98a4-b8dd27e30533'	System	13 Sep 2020 17:01:56
User entered '97.5'	System	13 Sep 2020 17:01:56

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:11', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'bd2c11b2-954e-47d4-98a4-b8dd27e30533'	System	13 Sep 2020 17:01:56
User entered 'No (N)'	System	13 Sep 2020 17:01:56

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:17', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'bd2c11b2-954e-47d4-98a4-b8dd27e30533'	System	13 Sep 2020 17:01:56
User entered '13 Sep 2020 12:02'	System	13 Sep 2020 17:01:56

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 5'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:03:12', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '33b6c1df-515a-4a8b-88a7-a31fc65253b5'	System	14 Sep 2020 17:04:09
User entered 'Yes (Y)'	System	14 Sep 2020 17:04:09

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:03:17', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '33b6c1df-515a-4a8b-88a7-a31fc65253b5'	System	14 Sep 2020 17:04:09
User entered '97.7'	System	14 Sep 2020 17:04:09

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:03:22', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '33b6c1df-515a-4a8b-88a7-a31fc65253b5'	System	14 Sep 2020 17:04:09
User entered 'No (N)'	System	14 Sep 2020 17:04:09

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:03:28', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '33b6c1df-515a-4a8b-88a7-a31fc65253b5'	System	14 Sep 2020 17:04:09
User entered '14 Sep 2020 12:03'	System	14 Sep 2020 17:04:09

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 6'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:00:40', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '77a1fde7-27af-422e-86fc-96d4f2aba7de'	System	15 Sep 2020 16:59:54
User entered 'Yes (Y)'	System	15 Sep 2020 16:59:54

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:00:45', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '77a1fde7-27af-422e-86fc-96d4f2aba7de' User entered '97.5'	System	15 Sep 2020 16:59:54
	System	15 Sep 2020 16:59:54

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:00:48', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '77a1fde7-27af-422e-86fc-96d4f2aba7de'	System	15 Sep 2020 16:59:54
User entered 'No (N)'	System	15 Sep 2020 16:59:54

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:00:53', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '77a1fde7-27af-422e-86fc-96d4f2aba7de'	System	15 Sep 2020 16:59:54
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 16:59:54

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 7'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:02:22', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '41e7726a-6f14-4523-bd32-89d4687d7025'	System	16 Sep 2020 17:02:34
User entered 'Yes (Y)'	System	16 Sep 2020 17:02:34

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:02:29', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '41e7726a-6f14-4523-bd32-89d4687d7025'	System	16 Sep 2020 17:02:34
User entered '98.1'	System	16 Sep 2020 17:02:34

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:02:33', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '41e7726a-6f14-4523-bd32-89d4687d7025'	System	16 Sep 2020 17:02:34
User entered 'No (N)'	System	16 Sep 2020 17:02:34

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:02:36', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '41e7726a-6f14-4523-bd32-89d4687d7025'	System	16 Sep 2020 17:02:34
User entered '16 Sep 2020 12:02'	System	16 Sep 2020 17:02:34

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:03', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'a65c0f18-abba-4be4-89d5-8b51d5eac545'	System	10 Sep 2020 14:04:34
User entered 'None (1)'	System	10 Sep 2020 14:04:34

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:06', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'a65c0f18-abba-4be4-89d5-8b51d5eac545'	System	10 Sep 2020 14:04:34
User entered 'No (N)'	System	10 Sep 2020 14:04:34

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:09', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'a65c0f18-abba-4be4-89d5-8b51d5eac545'	System	10 Sep 2020 14:04:34
User entered 'No (N)'	System	10 Sep 2020 14:04:34

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:13', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'a65c0f18-abba-4be4-89d5-8b51d5eac545'	System	10 Sep 2020 14:04:34
User entered 'None (1)'	System	10 Sep 2020 14:04:34

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:17', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'a65c0f18-abba-4be4-89d5-8b51d5eac545'	System	10 Sep 2020 14:04:34
User entered '10 Sep 2020 09:05'	System	10 Sep 2020 14:04:34

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Sep 2020 08:47'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Sep 2020 11:17'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:31:32', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f4b15e1-6238-48be-8c4c-2a81e41333d4'	System	11 Sep 2020 01:31:02
User entered 'None (1)'	System	11 Sep 2020 01:31:02

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:31:36', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f4b15e1-6238-48be-8c4c-2a81e41333d4'	System	11 Sep 2020 01:31:02
User entered 'No (N)'	System	11 Sep 2020 01:31:02

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:31:40', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f4b15e1-6238-48be-8c4c-2a81e41333d4'	System	11 Sep 2020 01:31:02
User entered 'No (N)'	System	11 Sep 2020 01:31:02

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:31:44', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f4b15e1-6238-48be-8c4c-2a81e41333d4'	System	11 Sep 2020 01:31:02
User entered 'None (1)'	System	11 Sep 2020 01:31:02

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:31:49', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f4b15e1-6238-48be-8c4c-2a81e41333d4'	System	11 Sep 2020 01:31:02
User entered '10 Sep 2020 20:31'	System	11 Sep 2020 01:31:02

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Sep 2020 12:12'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 2'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:12', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5338bea1-5b75-4b99-9b94-e091aafdf698'	System	11 Sep 2020 17:04:04
User entered 'None (1)'	System	11 Sep 2020 17:04:04

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:15', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5338bea1-5b75-4b99-9b94-e091aafdf698'	System	11 Sep 2020 17:04:04
User entered 'No (N)'	System	11 Sep 2020 17:04:04

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:19', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5338bea1-5b75-4b99-9b94-e091aafdf698'	System	11 Sep 2020 17:04:04
User entered 'No (N)'	System	11 Sep 2020 17:04:04

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:26', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5338bea1-5b75-4b99-9b94-e091aafdf698'	System	11 Sep 2020 17:04:04
User entered 'None (1)'	System	11 Sep 2020 17:04:04

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:32', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5338bea1-5b75-4b99-9b94-e091aafdf698'	System	11 Sep 2020 17:04:04
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 17:04:04

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 3'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:01:52', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '893bf7fb-34f6-4a5d-8031-ef40d6f006c3'	System	12 Sep 2020 17:01:59
User entered 'None (1)'	System	12 Sep 2020 17:01:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:01:55', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '893bf7fb-34f6-4a5d-8031-ef40d6f006c3'	System	12 Sep 2020 17:01:59
User entered 'No (N)'	System	12 Sep 2020 17:01:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:02', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '893bf7fb-34f6-4a5d-8031-ef40d6f006c3'	System	12 Sep 2020 17:01:59
User entered 'No (N)'	System	12 Sep 2020 17:01:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:05', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '893bf7fb-34f6-4a5d-8031-ef40d6f006c3'	System	12 Sep 2020 17:01:59
User entered 'None (1)'	System	12 Sep 2020 17:01:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:13', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '893bf7fb-34f6-4a5d-8031-ef40d6f006c3'	System	12 Sep 2020 17:01:59
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:01:59

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 4'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:24', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'cf7fead4-5b1c-4e26-bde2-40bc88f8d2a8'	System	13 Sep 2020 17:02:26
User entered 'None (1)'	System	13 Sep 2020 17:02:26

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:28', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'cf7fead4-5b1c-4e26-bde2-40bc88f8d2a8'	System	13 Sep 2020 17:02:26
User entered 'No (N)'	System	13 Sep 2020 17:02:26

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:32', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'cf7fead4-5b1c-4e26-bde2-40bc88f8d2a8'	System	13 Sep 2020 17:02:26
User entered 'No (N)'	System	13 Sep 2020 17:02:26

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:36', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'cf7fead4-5b1c-4e26-bde2-40bc88f8d2a8'	System	13 Sep 2020 17:02:26
User entered 'None (1)'	System	13 Sep 2020 17:02:26

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:41', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'cf7fead4-5b1c-4e26-bde2-40bc88f8d2a8'	System	13 Sep 2020 17:02:26
User entered '13 Sep 2020 12:02'	System	13 Sep 2020 17:02:26

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 5'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:03:46', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b59f90d3-b5da-4ac0-9ac5-cec06e98ee41'	System	14 Sep 2020 17:04:37
User entered 'None (1)'	System	14 Sep 2020 17:04:37

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:03:49', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b59f90d3-b5da-4ae0-9ac5-cec06e98ee41'	System	14 Sep 2020 17:04:37
User entered 'No (N)'	System	14 Sep 2020 17:04:37

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:03:53', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b59f90d3-b5da-4ae0-9ac5-cec06e98ee41'	System	14 Sep 2020 17:04:37
User entered 'No (N)'	System	14 Sep 2020 17:04:37

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:03:58', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b59f90d3-b5da-4ac0-9ac5-cec06e98ee41'	System	14 Sep 2020 17:04:37
User entered 'None (1)'	System	14 Sep 2020 17:04:37

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:04:04', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b59f90d3-b5da-4ae0-9ac5-cec06e98ee41'	System	14 Sep 2020 17:04:37
User entered '14 Sep 2020 12:04'	System	14 Sep 2020 17:04:37

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 6'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:00:59', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '307a2bdd-13d3-44d4-8ec1-9c840bb59adc'	System	15 Sep 2020 17:00:16
User entered 'None (1)'	System	15 Sep 2020 17:00:16

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:02', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '307a2bdd-13d3-44d4-8ec1-9c840bb59adc'	System	15 Sep 2020 17:00:16
User entered 'No (N)'	System	15 Sep 2020 17:00:16

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:05', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '307a2bdd-13d3-44d4-8ec1-9c840bb59adc'	System	15 Sep 2020 17:00:16
User entered 'No (N)'	System	15 Sep 2020 17:00:16

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:11', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '307a2bdd-13d3-44d4-8ec1-9c840bb59adc'	System	15 Sep 2020 17:00:16
User entered 'None (1)'	System	15 Sep 2020 17:00:16

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:14', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '307a2bdd-13d3-44d4-8ec1-9c840bb59adc'	System	15 Sep 2020 17:00:16
User entered '15 Sep 2020 12:01'	System	15 Sep 2020 17:00:16

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 7'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:02:41', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7f271eb5-532e-4ad6-8cc7-1f633d7915b4'	System	16 Sep 2020 17:03:10
User entered 'None (1)'	System	16 Sep 2020 17:03:10

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:02:44', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7f271eb5-532e-4ad6-8cc7-1f633d7915b4'	System	16 Sep 2020 17:03:10
User entered 'No (N)'	System	16 Sep 2020 17:03:10

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:02:47', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7f271eb5-532e-4ad6-8cc7-1f633d7915b4'	System	16 Sep 2020 17:03:10
User entered 'No (N)'	System	16 Sep 2020 17:03:10

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:08', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7f271eb5-532e-4ad6-8cc7-1f633d7915b4'	System	16 Sep 2020 17:03:10
User entered 'None (1)'	System	16 Sep 2020 17:03:10

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:13', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7f271eb5-532e-4ad6-8cc7-1f633d7915b4'	System	16 Sep 2020 17:03:10
User entered '16 Sep 2020 12:03'	System	16 Sep 2020 17:03:10

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:22', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8289546f-dd6f-4b3a-baa7-055f9bc1cff0'	System	10 Sep 2020 14:05:24
User entered 'None (0)'	System	10 Sep 2020 14:05:24

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:25', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8289546f-dd6f-4b3a-baa7-055f9bc1cff0'	System	10 Sep 2020 14:05:24
User entered 'None (0)'	System	10 Sep 2020 14:05:24

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:28', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8289546f-dd6f-4b3a-baa7-055f9bc1cff0'	System	10 Sep 2020 14:05:24
User entered 'None (0)'	System	10 Sep 2020 14:05:24

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:31', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8289546f-dd6f-4b3a-baa7-055f9bc1cff0'	System	10 Sep 2020 14:05:24
User entered 'None (0)'	System	10 Sep 2020 14:05:24

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:34', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8289546f-dd6f-4b3a-baa7-055f9bc1cff0'	System	10 Sep 2020 14:05:24
User entered 'None (0)'	System	10 Sep 2020 14:05:24

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:39', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8289546f-dd6f-4b3a-baa7-055f9bc1cff0'	System	10 Sep 2020 14:05:24
User entered 'None (0)'	System	10 Sep 2020 14:05:24

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:05:59', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8289546f-dd6f-4b3a-baa7-055f9bc1cff0'	System	10 Sep 2020 14:05:24
User entered 'No (N)'	System	10 Sep 2020 14:05:24

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T09:06:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8289546f-dd6f-4b3a-baa7-055f9bc1cff0'	System	10 Sep 2020 14:05:24
User entered '10 Sep 2020 09:06'	System	10 Sep 2020 14:05:24

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '10 Sep 2020 08:47'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '10 Sep 2020 11:17'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:32:03', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c5c54c90-c1cf-4fbe-bd60-863645cc8a30'	System	11 Sep 2020 01:31:53
User entered 'None (0)'	System	11 Sep 2020 01:31:53

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:32:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c5c54c90-c1cf-4fbe-bd60-863645cc8a30'	System	11 Sep 2020 01:31:53
User entered 'None (0)'	System	11 Sep 2020 01:31:53

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:32:11', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c5c54c90-c1cf-4fbe-bd60-863645cc8a30'	System	11 Sep 2020 01:31:53
User entered 'None (0)'	System	11 Sep 2020 01:31:53

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:32:14', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c5c54c90-c1cf-4fbe-bd60-863645cc8a30'	System	11 Sep 2020 01:31:53
User entered 'None (0)'	System	11 Sep 2020 01:31:53

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:32:18', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c5c54c90-c1cf-4fbe-bd60-863645cc8a30'	System	11 Sep 2020 01:31:53
User entered 'None (0)'	System	11 Sep 2020 01:31:53

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:32:23', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c5c54c90-c1cf-4fbe-bd60-863645cc8a30'	System	11 Sep 2020 01:31:53
User entered 'None (0)'	System	11 Sep 2020 01:31:53

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:32:36', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c5c54c90-c1cf-4fbe-bd60-863645cc8a30'	System	11 Sep 2020 01:31:53
User entered 'No (N)'	System	11 Sep 2020 01:31:53

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-10T20:32:39', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c5c54c90-c1cf-4fbe-bd60-863645cc8a30'	System	11 Sep 2020 01:31:53
User entered '10 Sep 2020 20:32'	System	11 Sep 2020 01:31:53

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '10 Sep 2020 12:12'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 2'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:40', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4163a980-b621-4f2e-bbde-cfe272b87021'	System	11 Sep 2020 17:04:29
User entered 'None (0)'	System	11 Sep 2020 17:04:29

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:42', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4163a980-b621-4f2e-bbde-cfe272b87021'	System	11 Sep 2020 17:04:29
User entered 'None (0)'	System	11 Sep 2020 17:04:29

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:45', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4163a980-b621-4f2e-bbde-cfe272b87021'	System	11 Sep 2020 17:04:29
User entered 'None (0)'	System	11 Sep 2020 17:04:29

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:48', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4163a980-b621-4f2e-bbde-cfe272b87021'	System	11 Sep 2020 17:04:29
User entered 'None (0)'	System	11 Sep 2020 17:04:29

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:51', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4163a980-b621-4f2e-bbde-cfe272b87021'	System	11 Sep 2020 17:04:29
User entered 'None (0)'	System	11 Sep 2020 17:04:29

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:03:55', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4163a980-b621-4f2e-bbde-cfe272b87021'	System	11 Sep 2020 17:04:29
User entered 'None (0)'	System	11 Sep 2020 17:04:29

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:04:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4163a980-b621-4f2e-bbde-cfe272b87021'	System	11 Sep 2020 17:04:29
User entered 'No (N)'	System	11 Sep 2020 17:04:29

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-11T12:04:04', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4163a980-b621-4f2e-bbde-cfe272b87021'	System	11 Sep 2020 17:04:29
User entered '11 Sep 2020 12:04'	System	11 Sep 2020 17:04:29

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 3'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:18', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '949df3c0-b437-44cb-9820-51591667bbf9'	System	12 Sep 2020 17:02:40
User entered 'None (0)'	System	12 Sep 2020 17:02:40

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:21', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '949df3c0-b437-44cb-9820-51591667bbf9'	System	12 Sep 2020 17:02:40
User entered 'None (0)'	System	12 Sep 2020 17:02:40

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:24', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '949df3c0-b437-44cb-9820-51591667bbf9'	System	12 Sep 2020 17:02:40
User entered 'None (0)'	System	12 Sep 2020 17:02:40

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:28', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '949df3c0-b437-44cb-9820-51591667bbf9'	System	12 Sep 2020 17:02:40
User entered 'None (0)'	System	12 Sep 2020 17:02:40

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:31', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '949df3c0-b437-44cb-9820-51591667bbf9'	System	12 Sep 2020 17:02:40
User entered 'None (0)'	System	12 Sep 2020 17:02:40

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:34', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '949df3c0-b437-44cb-9820-51591667bbf9'	System	12 Sep 2020 17:02:40
User entered 'None (0)'	System	12 Sep 2020 17:02:40

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:39', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '949df3c0-b437-44cb-9820-51591667bbf9'	System	12 Sep 2020 17:02:40
User entered 'No (N)'	System	12 Sep 2020 17:02:40

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-12T12:02:42', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '949df3c0-b437-44cb-9820-51591667bbf9'	System	12 Sep 2020 17:02:40
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:02:40

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 4'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:47', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '405d6cd5-d5e2-4859-93ff-eda9eb809c03'	System	13 Sep 2020 17:03:01
User entered 'None (0)'	System	13 Sep 2020 17:03:01

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:52', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '405d6cd5-d5e2-4859-93ff-eda9eb809c03'	System	13 Sep 2020 17:03:01
User entered 'None (0)'	System	13 Sep 2020 17:03:01

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:02:55', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '405d6cd5-d5e2-4859-93ff-eda9eb809c03'	System	13 Sep 2020 17:03:01
User entered 'None (0)'	System	13 Sep 2020 17:03:01

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:03:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '405d6cd5-d5e2-4859-93ff-eda9eb809c03'	System	13 Sep 2020 17:03:01
User entered 'None (0)'	System	13 Sep 2020 17:03:01

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:03:03', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '405d6cd5-d5e2-4859-93ff-eda9eb809c03'	System	13 Sep 2020 17:03:01
User entered 'None (0)'	System	13 Sep 2020 17:03:01

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:03:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '405d6cd5-d5e2-4859-93ff-eda9eb809c03'	System	13 Sep 2020 17:03:01
User entered 'None (0)'	System	13 Sep 2020 17:03:01

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:03:13', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '405d6cd5-d5e2-4859-93ff-eda9eb809c03'	System	13 Sep 2020 17:03:01
User entered 'No (N)'	System	13 Sep 2020 17:03:01

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-13T12:03:16', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '405d6cd5-d5e2-4859-93ff-eda9eb809c03'	System	13 Sep 2020 17:03:01
User entered '13 Sep 2020 12:03'	System	13 Sep 2020 17:03:01

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 5'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:04:22', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8556b45f-44bf-4cd5-b737-11c91d1cc41d'	System	14 Sep 2020 17:05:09
User entered 'None (0)'	System	14 Sep 2020 17:05:09

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:04:26', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8556b45f-44bf-4cd5-b737-11c91d1cc41d'	System	14 Sep 2020 17:05:09
User entered 'None (0)'	System	14 Sep 2020 17:05:09

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:04:29', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8556b45f-44bf-4cd5-b737-11c91d1cc41d'	System	14 Sep 2020 17:05:09
User entered 'None (0)'	System	14 Sep 2020 17:05:09

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:04:31', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8556b45f-44bf-4cd5-b737-11c91d1cc41d'	System	14 Sep 2020 17:05:09
User entered 'None (0)'	System	14 Sep 2020 17:05:09

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:04:34', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8556b45f-44bf-4cd5-b737-11c91d1cc41d'	System	14 Sep 2020 17:05:09
User entered 'None (0)'	System	14 Sep 2020 17:05:09

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:04:37', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8556b45f-44bf-4cd5-b737-11c91d1cc41d'	System	14 Sep 2020 17:05:09
User entered 'None (0)'	System	14 Sep 2020 17:05:09

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:04:42', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8556b45f-44bf-4cd5-b737-11c91d1cc41d'	System	14 Sep 2020 17:05:09
User entered 'No (N)'	System	14 Sep 2020 17:05:09

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-14T12:04:48', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8556b45f-44bf-4cd5-b737-11c91d1cc41d'	System	14 Sep 2020 17:05:09
User entered '14 Sep 2020 12:04'	System	14 Sep 2020 17:05:09

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 6'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:27', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9da3bf38-5498-4e2e-9675-d7deb778a6e6'	System	15 Sep 2020 17:01:30
User entered 'None (0)'	System	15 Sep 2020 17:01:30

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:30', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9da3bf38-5498-4e2e-9675-d7deb778a6e6'	System	15 Sep 2020 17:01:30
User entered 'None (0)'	System	15 Sep 2020 17:01:30

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:34', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9da3bf38-5498-4e2e-9675-d7deb778a6e6'	System	15 Sep 2020 17:01:30
User entered 'None (0)'	System	15 Sep 2020 17:01:30

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:37', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9da3bf38-5498-4e2e-9675-d7deb778a6e6'	System	15 Sep 2020 17:01:30
User entered 'None (0)'	System	15 Sep 2020 17:01:30

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:41', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9da3bf38-5498-4e2e-9675-d7deb778a6e6'	System	15 Sep 2020 17:01:30
User entered 'None (0)'	System	15 Sep 2020 17:01:30

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:44', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9da3bf38-5498-4e2e-9675-d7deb778a6e6'	System	15 Sep 2020 17:01:30
User entered 'None (0)'	System	15 Sep 2020 17:01:30

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:52', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9da3bf38-5498-4e2e-9675-d7deb778a6e6'	System	15 Sep 2020 17:01:30
User entered 'No (N)'	System	15 Sep 2020 17:01:30

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-15T12:01:55', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9da3bf38-5498-4e2e-9675-d7deb778a6e6'	System	15 Sep 2020 17:01:30
User entered '15 Sep 2020 12:01'	System	15 Sep 2020 17:01:30

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 7'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:19', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de170a7d-8be8-4604-8e66-2e6c27f6db2f'	System	16 Sep 2020 17:03:27
User entered 'None (0)'	System	16 Sep 2020 17:03:27

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:21', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de170a7d-8be8-4604-8e66-2e6c27f6db2f'	System	16 Sep 2020 17:03:27
User entered 'None (0)'	System	16 Sep 2020 17:03:27

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:24', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de170a7d-8be8-4604-8e66-2e6c27f6db2f'	System	16 Sep 2020 17:03:27
User entered 'None (0)'	System	16 Sep 2020 17:03:27

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:27', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de170a7d-8be8-4604-8e66-2e6c27f6db2f'	System	16 Sep 2020 17:03:27
User entered 'None (0)'	System	16 Sep 2020 17:03:27

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:30', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de170a7d-8be8-4604-8e66-2e6c27f6db2f'	System	16 Sep 2020 17:03:27
User entered 'None (0)'	System	16 Sep 2020 17:03:27

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:33', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de170a7d-8be8-4604-8e66-2e6c27f6db2f'	System	16 Sep 2020 17:03:27
User entered 'None (0)'	System	16 Sep 2020 17:03:27

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:39', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de170a7d-8be8-4604-8e66-2e6c27f6db2f'	System	16 Sep 2020 17:03:27
User entered 'No (N)'	System	16 Sep 2020 17:03:27

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-09-16T12:03:42', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de170a7d-8be8-4604-8e66-2e6c27f6db2f'	System	16 Sep 2020 17:03:27
User entered '16 Sep 2020 12:03'	System	16 Sep 2020 17:03:27

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 13:35:39

US3572170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:02
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:54
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 13:48:17

US3572170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:54
User entered '17 Sep 2020'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 13:48:17

US3572170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:54
User entered 'Contact Made (CONTACT MADE)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 13:48:17

US3572170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:54
User entered empty.	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 13:48:17

US3572170

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:31:58
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	18 Sep 2020 13:48:23

US3572170

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User entered 'l'	System	18 Sep 2020 13:48:23

US3572170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:08
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	24 Sep 2020 15:57:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	24 Sep 2020 15:57:01
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	24 Sep 2020 15:55:28
User entered 'No (N)'	Jessica Mcdowell (b) (4)	24 Sep 2020 15:55:28

US3572170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:08
User entered '24 Sep 2020'	Jessica McDowell (b) (4) (b) (4)	24 Sep 2020 15:55:28

US3572170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:32:08
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	24 Sep 2020 15:55:28

US3572170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:08
User entered empty.	Jessica McDowell (b) (4) (b) (4)	24 Sep 2020 15:55:28

US3572170

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:32:12
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	24 Sep 2020 15:57:06

US3572170

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:21
User entered 'l'	System	24 Sep 2020 15:57:06

US3572170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:15
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:25
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	01 Oct 2020 18:29:02

US3572170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:15
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:32:25
User entered '1 Oct 2020'	Martha Bunnell-Pollak	01 Oct 2020 18:29:02
	(b) (4)	

US3572170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:15
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:32:25
User entered 'Contact Made (CONTACT MADE)'	Martha Bunnell-Pollak	01 Oct 2020 18:29:02
	(b) (4)	

US3572170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:15
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:32:25
User entered empty.	Martha Bunnell-Pollak	01 Oct 2020 18:29:02
	(b) (4)	

US3572170

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:15
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:29
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	01 Oct 2020 18:28:52

US3572170

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:15
User entered 'l'	System	01 Oct 2020 18:28:52

US3572170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:43:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 02:27:15

US3572170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:43:12
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 02:27:15

US3572170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:43:12
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Oct 2020 02:27:15

US3572170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'VISIT2'	System	14 Oct 2020 02:27:15

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:17:15
User closed query 'Per source, 0950 is noted. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 22:17:13
Query 'Per source, 0950 is noted. Please review and reconcile.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 23:37:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 23:37:24
User entered '09:50' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:37:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:55:00
User opened query 'Per source, 0950 is noted. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:46:53
User entered '9:50'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered '08 Oct 2020 09:50'	System	16 Dec 2020 23:37:24
User entered '08 Oct 2020 9:50'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '97.7' F	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered 'Other (Other)'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered 'Temporal'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '53'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'bpm'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '20'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'breaths/min'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '163'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'mmHg'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '69'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'mmHg'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '10:57'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered '08 Oct 2020 10:57'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '97.9' F	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered 'Other (Other)'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered 'Temporal'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '53'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'bpm'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '18'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'breaths/min'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '133'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'mmHg'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:55:00
User entered '78'	(b) (4), (b) (6)	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'mmHg'	System	14 Oct 2020 02:29:10

US3572170

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 02:29:25

US3572170

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:28
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 02:29:25

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:38
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Nov 2020 19:56:38
User entered empty.	Alisha Lutat (b) (4) (b) (4)	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:38
User entered empty.	Alisha Lutat (b) (4) (b) (4)	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:38
User entered '8 Oct 2020'	Alisha Lutat (b) (4) (b) (4)	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:38
User entered '10:27'	Alisha Lutat (b) (4) (b) (4)	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered '8 Oct 2020 10:27'	System	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:38
User entered 'Left Arm (LEFT ARM)'	Alisha Lutat (b) (4) (b) (4)	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:56:38
User entered 'ONCE'	System	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 15:30:24

US3572170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 02:29:44

US3572170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:43
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 02:29:44

US3572170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:56:43
User entered '10:00'	(b) (4), (b) (6)	14 Oct 2020 02:29:44

US3572170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered '08 Oct 2020 10:00'	System	14 Oct 2020 02:29:44

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:17:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:12
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 02:30:02

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Oct 2020 02:30:02

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 02:30:02

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 22:16:52
User closed query 'Per source, 0956 is noted. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 22:16:50
Query 'Per source, 0956 is noted. Please review and reconcile.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 23:38:35
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 23:38:28
User entered '09:56' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:38:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:57:12
User opened query 'Per source, 0956 is noted. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:57:06
User entered '9:56'	(b) (4), (b) (6)	14 Oct 2020 02:30:02

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered '08 Oct 2020 09:56'	System	16 Dec 2020 23:38:28
User entered '08 Oct 2020 9:56'	System	14 Oct 2020 02:30:02

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Oct 2020 02:30:02

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:12
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 02:30:02

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:12
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 02:30:02

US3572170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered empty.	System	14 Oct 2020 02:30:02

US3572170

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 02:30:07

US3572170

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'l'	System	14 Oct 2020 02:30:07

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:55:31', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '79a77219-e873-48e1-b2d8-f25eb7257bd1'	System	08 Oct 2020 15:53:56
User entered 'Yes (Y)'	System	08 Oct 2020 15:53:56

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:55:38', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '79a77219-e873-48e1-b2d8-f25eb7257bd1' User entered '97.9'	System	08 Oct 2020 15:53:56
	System	08 Oct 2020 15:53:56

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:55:41', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '79a77219-e873-48e1-b2d8-f25eb7257bd1'	System	08 Oct 2020 15:53:56
User entered 'No (N)'	System	08 Oct 2020 15:53:56

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:55:47', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '79a77219-e873-48e1-b2d8-f25eb7257bd1'	System	08 Oct 2020 15:53:56
User entered '08 Oct 2020 10:55'	System	08 Oct 2020 15:53:56

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '08 Oct 2020 10:47'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '08 Oct 2020 13:17'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:35:51', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7214b13c-71bf-49bd-9bdb-a916d8dae87a'	System	08 Oct 2020 22:34:19
User entered 'Yes (Y)'	System	08 Oct 2020 22:34:19

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:35:57', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7214b13c-71bf-49bd-9bdb-a916d8dae87a' User entered '97.7'	System	08 Oct 2020 22:34:19
	System	08 Oct 2020 22:34:19

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:36:03', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7214b13c-71bf-49bd-9bdb-a916d8dae87a'	System	08 Oct 2020 22:34:19
User entered 'No (N)'	System	08 Oct 2020 22:34:19

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:36:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7214b13c-71bf-49bd-9bdb-a916d8dae87a'	System	08 Oct 2020 22:34:19
User entered '08 Oct 2020 17:36'	System	08 Oct 2020 22:34:19

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '08 Oct 2020 14:12'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 2'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:09:58', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd266d67b-ac0b-4d2d-be68-f9f4701f40ad'	System	10 Oct 2020 11:08:22
User entered 'Yes (Y)'	System	10 Oct 2020 11:08:22

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:04', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd266d67b-ac0b-4d2d-be68-f9f4701f40ad'	System	10 Oct 2020 11:08:22
User entered '97.7'	System	10 Oct 2020 11:08:22

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:09', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd266d67b-ac0b-4d2d-be68-f9f4701f40ad'	System	10 Oct 2020 11:08:22
User entered 'No (N)'	System	10 Oct 2020 11:08:22

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:16', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd266d67b-ae0b-4d2d-be68-f9f4701f40ad'	System	10 Oct 2020 11:08:22
User entered '10 Oct 2020 06:10'	System	10 Oct 2020 11:08:22

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 3'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:27:57', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e56317de-6024-4e06-886d-3e522321072a'	System	10 Oct 2020 21:26:10
User entered 'Yes (Y)'	System	10 Oct 2020 21:26:10

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:01', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e56317de-6024-4e06-886d-3e522321072a' User entered '98.0'	System	10 Oct 2020 21:26:10
	System	10 Oct 2020 21:26:10

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:05', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e56317de-6024-4e06-886d-3e522321072a'	System	10 Oct 2020 21:26:10
User entered 'No (N)'	System	10 Oct 2020 21:26:10

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:09', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e56317de-6024-4e06-886d-3e522321072a'	System	10 Oct 2020 21:26:10
User entered '10 Oct 2020 16:28'	System	10 Oct 2020 21:26:10

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 4'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:51:44', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c35d5af1-e3dc-4a5c-a214-cba725c5207d'	System	12 Oct 2020 01:49:58
User entered 'Yes (Y)'	System	12 Oct 2020 01:49:58

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:51:50', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c35d5af1-e3dc-4a5c-a214-cba725c5207d'	System	12 Oct 2020 01:49:58
User entered '97.7'	System	12 Oct 2020 01:49:58

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:51:55', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c35d5af1-e3dc-4a5c-a214-cba725c5207d'	System	12 Oct 2020 01:49:58
User entered 'No (N)'	System	12 Oct 2020 01:49:58

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:51:58', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c35d5af1-e3dc-4a5c-a214-cba725c5207d'	System	12 Oct 2020 01:49:58
User entered '11 Oct 2020 20:51'	System	12 Oct 2020 01:49:58

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 5'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:16:48', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6a79c3dc-e4d8-41de-bbf3-c468df8b8a58'	System	12 Oct 2020 21:14:59
User entered 'Yes (Y)'	System	12 Oct 2020 21:14:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:16:53', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6a79c3dc-e4d8-41de-bbf3-c468df8b8a58'	System	12 Oct 2020 21:14:59
User entered '98.2'	System	12 Oct 2020 21:14:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:16:57', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6a79c3dc-e4d8-41de-bbf3-c468df8b8a58'	System	12 Oct 2020 21:14:59
User entered 'No (N)'	System	12 Oct 2020 21:14:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:01', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6a79c3dc-e4d8-41de-bbf3-c468df8b8a58'	System	12 Oct 2020 21:14:59
User entered '12 Oct 2020 16:17'	System	12 Oct 2020 21:14:59

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 6'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:07:55', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7532a217-162e-46f6-87e5-7d1a1a70acf7'	System	14 Oct 2020 13:06:02
User entered 'Yes (Y)'	System	14 Oct 2020 13:06:02

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7532a217-162e-46f6-87e5-7d1a1a70acf7'	System	14 Oct 2020 13:06:02
User entered '98.2'	System	14 Oct 2020 13:06:02

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:04', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7532a217-162e-46f6-87e5-7d1a1a70acf7'	System	14 Oct 2020 13:06:02
User entered 'No (N)'	System	14 Oct 2020 13:06:02

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '7532a217-162e-46f6-87e5-7d1a1a70acf7'	System	14 Oct 2020 13:06:02
User entered '14 Oct 2020 08:08'	System	14 Oct 2020 13:06:02

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 7'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:15:45', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '0413007a-6396-4292-8ab2-9bb24e82e3db'	System	14 Oct 2020 17:14:18
User entered 'Yes (Y)'	System	14 Oct 2020 17:14:18

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:15:52', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '0413007a-6396-4292-8ab2-9bb24e82e3db' User entered '97.1'	System	14 Oct 2020 17:14:18
	System	14 Oct 2020 17:14:18

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:15:56', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '0413007a-6396-4292-8ab2-9bb24e82e3db'	System	14 Oct 2020 17:14:18
User entered 'No (N)'	System	14 Oct 2020 17:14:18

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:01', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '0413007a-6396-4292-8ab2-9bb24e82e3db'	System	14 Oct 2020 17:14:18
User entered '14 Oct 2020 12:16'	System	14 Oct 2020 17:14:18

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:55:56', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '1f603794-16e0-4350-b37d-cafe4700ffff'	System	08 Oct 2020 15:54:22
User entered 'None (1)'	System	08 Oct 2020 15:54:22

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:02', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '1f603794-16e0-4350-b37d-cafe4700ffff'	System	08 Oct 2020 15:54:22
User entered 'No (N)'	System	08 Oct 2020 15:54:22

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:06', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '1f603794-16e0-4350-b37d-cafe4700ffff'	System	08 Oct 2020 15:54:22
User entered 'No (N)'	System	08 Oct 2020 15:54:22

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:10', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '1f603794-16e0-4350-b37d-cafe4700ffff'	System	08 Oct 2020 15:54:22
User entered 'None (1)'	System	08 Oct 2020 15:54:22

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:13', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '1f603794-16e0-4350-b37d-cafe4700ffff'	System	08 Oct 2020 15:54:22
User entered '08 Oct 2020 10:56'	System	08 Oct 2020 15:54:22

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '08 Oct 2020 10:47'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '08 Oct 2020 13:17'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:36:19', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '40fbf7bd-1ed8-4575-aeef-16c6dfed3838'	System	08 Oct 2020 22:35:05
User entered 'None (1)'	System	08 Oct 2020 22:35:05

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:36:26', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '40fbf7bd-1ed8-4575-aeef-16c6dfed3838'	System	08 Oct 2020 22:35:05
User entered 'No (N)'	System	08 Oct 2020 22:35:05

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:36:30', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '40fbf7bd-1ed8-4575-aeef-16c6dfed3838'	System	08 Oct 2020 22:35:05
User entered 'No (N)'	System	08 Oct 2020 22:35:05

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:36:46', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '40fbf7bd-1ed8-4575-aeef-16c6dfed3838'	System	08 Oct 2020 22:35:05
User entered 'None (1)'	System	08 Oct 2020 22:35:05

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:36:58', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '40fbf7bd-1ed8-4575-aeef-16c6dfed3838'	System	08 Oct 2020 22:35:05
User entered '08 Oct 2020 17:36'	System	08 Oct 2020 22:35:05

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '08 Oct 2020 14:12'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 2'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:23', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6ce9c583-b84d-448f-920d-317fda6877b9'	System	10 Oct 2020 11:08:49
User entered 'None (1)'	System	10 Oct 2020 11:08:49

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:27', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6ce9c583-b84d-448f-920d-317fda6877b9'	System	10 Oct 2020 11:08:49
User entered 'No (N)'	System	10 Oct 2020 11:08:49

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:31', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6ce9c583-b84d-448f-920d-317fda6877b9'	System	10 Oct 2020 11:08:49
User entered 'No (N)'	System	10 Oct 2020 11:08:49

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:41', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6ce9c583-b84d-448f-920d-317fda6877b9'	System	10 Oct 2020 11:08:49
User entered 'None (1)'	System	10 Oct 2020 11:08:49

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:45', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6ce9c583-b84d-448f-920d-317fda6877b9'	System	10 Oct 2020 11:08:49
User entered '10 Oct 2020 06:10'	System	10 Oct 2020 11:08:49

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 3'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:14', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f0b568b-8250-4371-95f3-27609db3dbdd'	System	10 Oct 2020 21:26:38
User entered 'None (1)'	System	10 Oct 2020 21:26:38

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:19', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f0b568b-8250-4371-95f3-27609db3dbdd'	System	10 Oct 2020 21:26:38
User entered 'No (N)'	System	10 Oct 2020 21:26:38

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:23', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f0b568b-8250-4371-95f3-27609db3dbdd'	System	10 Oct 2020 21:26:38
User entered 'No (N)'	System	10 Oct 2020 21:26:38

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:27', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f0b568b-8250-4371-95f3-27609db3dbdd'	System	10 Oct 2020 21:26:38
User entered 'None (1)'	System	10 Oct 2020 21:26:38

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:36', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '5f0b568b-8250-4371-95f3-27609db3dbdd'	System	10 Oct 2020 21:26:38
User entered '10 Oct 2020 16:28'	System	10 Oct 2020 21:26:38

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 4'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:04', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3ac6196b-caa0-4e49-bf0c-70ff4e744344'	System	12 Oct 2020 01:50:24
User entered 'None (1)'	System	12 Oct 2020 01:50:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:09', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3ac6196b-caa0-4e49-bf0c-70ff4e744344'	System	12 Oct 2020 01:50:24
User entered 'No (N)'	System	12 Oct 2020 01:50:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:13', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3ac6196b-caa0-4e49-bf0c-70ff4e744344'	System	12 Oct 2020 01:50:24
User entered 'No (N)'	System	12 Oct 2020 01:50:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:19', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3ac6196b-caa0-4e49-bf0c-70ff4e744344'	System	12 Oct 2020 01:50:24
User entered 'None (1)'	System	12 Oct 2020 01:50:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:24', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3ac6196b-caa0-4e49-bf0c-70ff4e744344'	System	12 Oct 2020 01:50:24
User entered '11 Oct 2020 20:52'	System	12 Oct 2020 01:50:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 5'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:09', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8f97c84f-21b7-4da9-aaed-60554aa99417'	System	12 Oct 2020 21:15:25
User entered 'None (1)'	System	12 Oct 2020 21:15:25

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:12', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8f97c84f-21b7-4da9-aaed-60554aa99417'	System	12 Oct 2020 21:15:25
User entered 'No (N)'	System	12 Oct 2020 21:15:25

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:16', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8f97c84f-21b7-4da9-aaed-60554aa99417'	System	12 Oct 2020 21:15:25
User entered 'No (N)'	System	12 Oct 2020 21:15:25

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:20', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8f97c84f-21b7-4da9-aaed-60554aa99417'	System	12 Oct 2020 21:15:25
User entered 'None (1)'	System	12 Oct 2020 21:15:25

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:29', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8f97c84f-21b7-4da9-aaed-60554aa99417'	System	12 Oct 2020 21:15:25
User entered '12 Oct 2020 16:17'	System	12 Oct 2020 21:15:25

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 6'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:12', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3694c209-3386-44c3-bb22-1d32ebb6aadf'	System	14 Oct 2020 13:06:21
User entered 'None (1)'	System	14 Oct 2020 13:06:21

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:16', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3694c209-3386-44c3-bb22-1d32ebb6aadf'	System	14 Oct 2020 13:06:21
User entered 'No (N)'	System	14 Oct 2020 13:06:21

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:19', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3694c209-3386-44c3-bb22-1d32ebb6aadf'	System	14 Oct 2020 13:06:21
User entered 'No (N)'	System	14 Oct 2020 13:06:21

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:25', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3694c209-3386-44c3-bb22-1d32ebb6aadf'	System	14 Oct 2020 13:06:21
User entered 'None (1)'	System	14 Oct 2020 13:06:21

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:28', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3694c209-3386-44c3-bb22-1d32ebb6aadf'	System	14 Oct 2020 13:06:21
User entered '14 Oct 2020 08:08'	System	14 Oct 2020 13:06:21

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 7'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd2d11df3-bf75-498f-8b95-6046a0ab775c'	System	14 Oct 2020 17:14:24
User entered 'None (1)'	System	14 Oct 2020 17:14:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:10', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd2d11df3-bf75-498f-8b95-6046a0ab775c'	System	14 Oct 2020 17:14:24
User entered 'No (N)'	System	14 Oct 2020 17:14:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:14', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd2d11df3-bf75-498f-8b95-6046a0ab775c'	System	14 Oct 2020 17:14:24
User entered 'No (N)'	System	14 Oct 2020 17:14:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:17', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd2d11df3-bf75-498f-8b95-6046a0ab775c'	System	14 Oct 2020 17:14:24
User entered 'None (1)'	System	14 Oct 2020 17:14:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:28', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd2d11df3-bf75-498f-8b95-6046a0ab775c'	System	14 Oct 2020 17:14:24
User entered '14 Oct 2020 12:16'	System	14 Oct 2020 17:14:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:19', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b62cef7a-2e88-428d-9cac-9d8892735199'	System	08 Oct 2020 22:33:52
User entered 'None (0)'	System	08 Oct 2020 22:33:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:26', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b62cef7a-2e88-428d-9cac-9d8892735199'	System	08 Oct 2020 22:33:52
User entered 'None (0)'	System	08 Oct 2020 22:33:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:28', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b62cef7a-2e88-428d-9cac-9d8892735199'	System	08 Oct 2020 22:33:52
User entered 'None (0)'	System	08 Oct 2020 22:33:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:31', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b62cef7a-2e88-428d-9cac-9d8892735199'	System	08 Oct 2020 22:33:52
User entered 'None (0)'	System	08 Oct 2020 22:33:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:33', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b62cef7a-2e88-428d-9cac-9d8892735199'	System	08 Oct 2020 22:33:52
User entered 'None (0)'	System	08 Oct 2020 22:33:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:35', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b62cef7a-2e88-428d-9cac-9d8892735199'	System	08 Oct 2020 22:33:52
User entered 'None (0)'	System	08 Oct 2020 22:33:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:39', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b62cef7a-2e88-428d-9cac-9d8892735199'	System	08 Oct 2020 22:33:52
User entered 'No (N)'	System	08 Oct 2020 22:33:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T10:56:43', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b62cef7a-2e88-428d-9cac-9d8892735199'	System	08 Oct 2020 22:33:52
User entered '08 Oct 2020 10:56'	System	08 Oct 2020 22:33:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '08 Oct 2020 10:47'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '08 Oct 2020 13:17'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:37:06', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f72241cf-9e47-4555-8438-89c6291a888b'	System	08 Oct 2020 22:36:07
User entered 'None (0)'	System	08 Oct 2020 22:36:07

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:37:11', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f72241cf-9e47-4555-8438-89c6291a888b'	System	08 Oct 2020 22:36:07
User entered 'None (0)'	System	08 Oct 2020 22:36:07

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:37:17', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f72241cf-9e47-4555-8438-89c6291a888b'	System	08 Oct 2020 22:36:07
User entered 'None (0)'	System	08 Oct 2020 22:36:07

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:37:21', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f72241cf-9e47-4555-8438-89c6291a888b'	System	08 Oct 2020 22:36:07
User entered 'None (0)'	System	08 Oct 2020 22:36:07

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:37:32', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f72241cf-9e47-4555-8438-89c6291a888b'	System	08 Oct 2020 22:36:07
User entered 'None (0)'	System	08 Oct 2020 22:36:07

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:37:39', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f72241cf-9e47-4555-8438-89c6291a888b'	System	08 Oct 2020 22:36:07
User entered 'None (0)'	System	08 Oct 2020 22:36:07

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:37:48', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f72241cf-9e47-4555-8438-89c6291a888b'	System	08 Oct 2020 22:36:07
User entered 'No (N)'	System	08 Oct 2020 22:36:07

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-08T17:38:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f72241cf-9e47-4555-8438-89c6291a888b'	System	08 Oct 2020 22:36:07
User entered '08 Oct 2020 17:38'	System	08 Oct 2020 22:36:07

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '08 Oct 2020 14:12'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 2'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:50', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ce61e1a1-edbc-4b53-a7de-7ad913cbbc54'	System	10 Oct 2020 11:09:16
User entered 'None (0)'	System	10 Oct 2020 11:09:16

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:54', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ce61e1a1-edbc-4b53-a7de-7ad913cbbc54'	System	10 Oct 2020 11:09:16
User entered 'None (0)'	System	10 Oct 2020 11:09:16

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:56', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ce61e1a1-edbc-4b53-a7de-7ad913cbbc54'	System	10 Oct 2020 11:09:16
User entered 'None (0)'	System	10 Oct 2020 11:09:16

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:10:59', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ce61e1a1-edbc-4b53-a7de-7ad913cbbc54'	System	10 Oct 2020 11:09:16
User entered 'None (0)'	System	10 Oct 2020 11:09:16

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:11:02', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ce61e1a1-edbc-4b53-a7de-7ad913cbbc54'	System	10 Oct 2020 11:09:16
User entered 'None (0)'	System	10 Oct 2020 11:09:16

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:11:05', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ce61e1a1-edbc-4b53-a7de-7ad913cbbc54'	System	10 Oct 2020 11:09:16
User entered 'None (0)'	System	10 Oct 2020 11:09:16

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:11:09', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ce61e1a1-edbc-4b53-a7de-7ad913cbbc54'	System	10 Oct 2020 11:09:16
User entered 'No (N)'	System	10 Oct 2020 11:09:16

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T06:11:12', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ce61e1a1-edbc-4b53-a7de-7ad913cbbc54'	System	10 Oct 2020 11:09:16
User entered '10 Oct 2020 06:11'	System	10 Oct 2020 11:09:16

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 3'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:41', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b1f04293-02f4-432a-88f2-e9a2de9d4a4c'	System	10 Oct 2020 21:27:12
User entered 'None (0)'	System	10 Oct 2020 21:27:12

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:45', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b1f04293-02f4-432a-88f2-e9a2de9d4a4c'	System	10 Oct 2020 21:27:12
User entered 'None (0)'	System	10 Oct 2020 21:27:12

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:48', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b1f04293-02f4-432a-88f2-e9a2de9d4a4c'	System	10 Oct 2020 21:27:12
User entered 'None (0)'	System	10 Oct 2020 21:27:12

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:52', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b1f04293-02f4-432a-88f2-e9a2de9d4a4c'	System	10 Oct 2020 21:27:12
User entered 'None (0)'	System	10 Oct 2020 21:27:12

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:28:55', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b1f04293-02f4-432a-88f2-e9a2de9d4a4c'	System	10 Oct 2020 21:27:12
User entered 'None (0)'	System	10 Oct 2020 21:27:12

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:29:02', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b1f04293-02f4-432a-88f2-e9a2de9d4a4c'	System	10 Oct 2020 21:27:12
User entered 'None (0)'	System	10 Oct 2020 21:27:12

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:29:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b1f04293-02f4-432a-88f2-e9a2de9d4a4c'	System	10 Oct 2020 21:27:12
User entered 'No (N)'	System	10 Oct 2020 21:27:12

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-10T16:29:10', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b1f04293-02f4-432a-88f2-e9a2de9d4a4c'	System	10 Oct 2020 21:27:12
User entered '10 Oct 2020 16:29'	System	10 Oct 2020 21:27:12

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 4'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:30', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e27d69a2-360d-400d-851c-7d70fcd01cfc'	System	12 Oct 2020 01:50:53
User entered 'None (0)'	System	12 Oct 2020 01:50:53

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:33', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e27d69a2-360d-400d-851c-7d70fcd01cfc'	System	12 Oct 2020 01:50:53
User entered 'None (0)'	System	12 Oct 2020 01:50:53

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:36', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e27d69a2-360d-400d-851c-7d70fcd01cfc'	System	12 Oct 2020 01:50:53
User entered 'None (0)'	System	12 Oct 2020 01:50:53

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:40', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e27d69a2-360d-400d-851c-7d70fcd01cfc'	System	12 Oct 2020 01:50:53
User entered 'None (0)'	System	12 Oct 2020 01:50:53

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:43', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e27d69a2-360d-400d-851c-7d70fcd01cfc'	System	12 Oct 2020 01:50:53
User entered 'None (0)'	System	12 Oct 2020 01:50:53

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:45', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e27d69a2-360d-400d-851c-7d70fcd01cfc'	System	12 Oct 2020 01:50:53
User entered 'None (0)'	System	12 Oct 2020 01:50:53

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:49', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e27d69a2-360d-400d-851c-7d70fcd01cfc'	System	12 Oct 2020 01:50:53
User entered 'No (N)'	System	12 Oct 2020 01:50:53

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-11T20:52:53', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e27d69a2-360d-400d-851c-7d70fcd01cfc'	System	12 Oct 2020 01:50:53
User entered '11 Oct 2020 20:52'	System	12 Oct 2020 01:50:53

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 5'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:34', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c12a546f-f2b7-4a4a-b8ab-b9c9825b470f' User entered 'None (0)'	System	12 Oct 2020 21:16:00
	System	12 Oct 2020 21:16:00

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:38', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c12a546f-f2b7-4a4a-b8ab-b9c9825b470f' User entered 'None (0)'	System	12 Oct 2020 21:16:00
	System	12 Oct 2020 21:16:00

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:41', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c12a546f-f2b7-4a4a-b8ab-b9c9825b470f'	System	12 Oct 2020 21:16:00
User entered 'None (0)'	System	12 Oct 2020 21:16:00

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:45', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c12a546f-f2b7-4a4a-b8ab-b9c9825b470f'	System	12 Oct 2020 21:16:00
User entered 'None (0)'	System	12 Oct 2020 21:16:00

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:48', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c12a546f-f2b7-4a4a-b8ab-b9c9825b470f'	System	12 Oct 2020 21:16:00
User entered 'None (0)'	System	12 Oct 2020 21:16:00

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:51', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c12a546f-f2b7-4a4a-b8ab-b9c9825b470f'	System	12 Oct 2020 21:16:00
User entered 'None (0)'	System	12 Oct 2020 21:16:00

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:17:58', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c12a546f-f2b7-4a4a-b8ab-b9c9825b470f'	System	12 Oct 2020 21:16:00
User entered 'No (N)'	System	12 Oct 2020 21:16:00

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-12T16:18:03', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'c12a546f-f2b7-4a4a-b8ab-b9c9825b470f'	System	12 Oct 2020 21:16:00
User entered '12 Oct 2020 16:18'	System	12 Oct 2020 21:16:00

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 6'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:34', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f02efcc0-df0e-4f09-9e7f-2cdf9a4a7b4b'	System	14 Oct 2020 13:06:51
User entered 'None (0)'	System	14 Oct 2020 13:06:51

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:37', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f02efcc0-df0e-4f09-9e7f-2cdf9a4a7b4b'	System	14 Oct 2020 13:06:51
User entered 'None (0)'	System	14 Oct 2020 13:06:51

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:40', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f02efcc0-df0e-4f09-9e7f-2cdf9a4a7b4b'	System	14 Oct 2020 13:06:51
User entered 'None (0)'	System	14 Oct 2020 13:06:51

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:43', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f02efcc0-df0e-4f09-9e7f-2cdf9a4a7b4b'	System	14 Oct 2020 13:06:51
User entered 'None (0)'	System	14 Oct 2020 13:06:51

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:46', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f02efcc0-df0e-4f09-9e7f-2cdf9a4a7b4b'	System	14 Oct 2020 13:06:51
User entered 'None (0)'	System	14 Oct 2020 13:06:51

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:49', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f02efcc0-df0e-4f09-9e7f-2cdf9a4a7b4b'	System	14 Oct 2020 13:06:51
User entered 'None (0)'	System	14 Oct 2020 13:06:51

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:54', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f02efcc0-df0e-4f09-9e7f-2cdf9a4a7b4b'	System	14 Oct 2020 13:06:51
User entered 'No (N)'	System	14 Oct 2020 13:06:51

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T08:08:57', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f02efcc0-df0e-4f09-9e7f-2cdf9a4a7b4b'	System	14 Oct 2020 13:06:51
User entered '14 Oct 2020 08:08'	System	14 Oct 2020 13:06:51

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	08 Oct 2020 15:30:24
User entered 'Day 7'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:35', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de6a8225-4171-4938-8494-2968bf132dfc'	System	14 Oct 2020 17:14:52
User entered 'None (0)'	System	14 Oct 2020 17:14:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:38', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de6a8225-4171-4938-8494-2968bf132dfc'	System	14 Oct 2020 17:14:52
User entered 'None (0)'	System	14 Oct 2020 17:14:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:41', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de6a8225-4171-4938-8494-2968bf132dfc'	System	14 Oct 2020 17:14:52
User entered 'None (0)'	System	14 Oct 2020 17:14:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:45', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de6a8225-4171-4938-8494-2968bf132dfc'	System	14 Oct 2020 17:14:52
User entered 'None (0)'	System	14 Oct 2020 17:14:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:48', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de6a8225-4171-4938-8494-2968bf132dfc'	System	14 Oct 2020 17:14:52
User entered 'None (0)'	System	14 Oct 2020 17:14:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:51', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de6a8225-4171-4938-8494-2968bf132dfc'	System	14 Oct 2020 17:14:52
User entered 'None (0)'	System	14 Oct 2020 17:14:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:55', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de6a8225-4171-4938-8494-2968bf132dfc'	System	14 Oct 2020 17:14:52
User entered 'No (N)'	System	14 Oct 2020 17:14:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-10-14T12:16:58', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de6a8225-4171-4938-8494-2968bf132dfc'	System	14 Oct 2020 17:14:52
User entered '14 Oct 2020 12:16'	System	14 Oct 2020 17:14:52

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 15:30:24

US3572170

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 15:30:24

US3572170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:50
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	15 Oct 2020 18:56:49

US3572170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:50
User entered '15 Oct 2020'	Martha Bunnell-Pollak (b) (4)	15 Oct 2020 18:56:49

US3572170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:50
User entered 'Contact Made (CONTACT MADE)'	Martha Bunnell-Pollak (b) (4)	15 Oct 2020 18:56:49

US3572170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:50
User entered empty.	Martha Bunnell-Pollak (b) (4)	15 Oct 2020 18:56:49

US3572170

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:57:54
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	15 Oct 2020 18:56:53

US3572170

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'l'	System	15 Oct 2020 18:56:53

US3572170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:08
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	22 Oct 2020 15:07:42

US3572170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:08
User entered '22 Oct 2020'	Martha Bunnell-Pollak (b) (4)	22 Oct 2020 15:07:42

US3572170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:08
User entered 'Contact Made (CONTACT MADE)'	Martha Bunnell-Pollak (b) (4)	22 Oct 2020 15:07:42

US3572170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:08
User entered empty.	Martha Bunnell-Pollak (b) (4)	22 Oct 2020 15:07:42

US3572170

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:12
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	22 Oct 2020 15:07:46

US3572170

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'l'	System	22 Oct 2020 15:07:46

US3572170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:23
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	29 Oct 2020 14:53:34

US3572170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:23
User entered '29 Oct 2020'	Martha Bunnell-Pollak (b) (4)	29 Oct 2020 14:53:34

US3572170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:23
User entered 'Contact Made (CONTACT MADE)'	Martha Bunnell-Pollak (b) (4)	29 Oct 2020 14:53:34

US3572170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:23
User entered empty.	Martha Bunnell-Pollak (b) (4)	29 Oct 2020 14:53:34

US3572170

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:58:27
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	29 Oct 2020 14:53:37

US3572170

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'l'	System	29 Oct 2020 14:53:37

US3572170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 23:32:17

US3572170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:15
User entered '6 Nov 2020'	(b) (4), (b) (6)	16 Dec 2020 23:32:17

US3572170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:15
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Dec 2020 23:32:17

US3572170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'VISIT3'	System	16 Dec 2020 23:32:17

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:02
User entered '6 Nov 2020'	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4)	16 Feb 2021 22:17:28
User closed query 'Per source, 0815 is noted. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 22:17:26
Query 'Per source, 0815 is noted. Please reconcile.' answered with 'reconciled' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 02:16:43
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 02:16:36
User entered '08:15' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 02:16:36
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:02
User opened query 'Per source, 0815 is noted. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:28:40
User entered '08:10'	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered '6 Nov 2020 08:15'	System	08 Jan 2021 02:16:36
User entered '6 Nov 2020 08:10'	System	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:02
User entered '97.5' F	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:02
User entered 'Other (Other)'	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:02
User entered 'TEMPORAL'	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:02
User entered '48'	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'bpm'	System	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:02
User entered '18'	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'breaths/min'	System	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:02
User entered '126'	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'mmHg'	System	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:02
User entered '67'	(b) (4), (b) (6)	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'mmHg'	System	16 Dec 2020 23:32:58

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41

US3572170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41

US3572170

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 23:33:08

US3572170

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:18
User entered '6 Nov 2020'	(b) (4), (b) (6)	16 Dec 2020 23:33:08

US3572170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 23:33:28

US3572170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:23
User entered '6 Nov 2020'	(b) (4), (b) (6)	16 Dec 2020 23:33:28

US3572170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:23
User entered '08:20'	(b) (4), (b) (6)	16 Dec 2020 23:33:28

US3572170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered '6 Nov 2020 08:20'	System	16 Dec 2020 23:33:28

US3572170

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:21
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 15:34:55
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 23:39:27
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 18:23:40
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	30 Nov 2020 20:44:23

US3572170

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'I'	System	30 Nov 2020 20:44:23

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 64'	System	10 Sep 2020 13:35:39

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-14T09:01:05', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '2f4e5d15-5a47-45b4-84aa-0f7853241bbe'	System	14 Nov 2020 15:00:49
User entered 'No (N)'	System	14 Nov 2020 15:00:49

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-14T09:01:13', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '2f4e5d15-5a47-45b4-84aa-0f7853241bbe'	System	14 Nov 2020 15:00:49
User entered 'No (N)'	System	14 Nov 2020 15:00:49

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-14T09:01:21', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '2f4e5d15-5a47-45b4-84aa-0f7853241bbe'	System	14 Nov 2020 15:00:49
User entered '14 Nov 2020 09:01:21'	System	14 Nov 2020 15:00:49

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 13:35:39

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered 'Day 71'	System	10 Sep 2020 13:35:39

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-17T06:52:04', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b76fbb88-a866-44e9-a079-ad535d469bca'	System	17 Nov 2020 12:51:43
User entered 'No (N)'	System	17 Nov 2020 12:51:43

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-17T06:52:15', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b76fbb88-a866-44e9-a079-ad535d469bca'	System	17 Nov 2020 12:51:43
User entered 'No (N)'	System	17 Nov 2020 12:51:43

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-17T06:52:21', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b76fbb88-a866-44e9-a079-ad535d469bca'	System	17 Nov 2020 12:51:43
User entered '17 Nov 2020 06:52:21'	System	17 Nov 2020 12:51:43

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 13:35:39

US3572170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:33:04
Data entry locked.	System	10 Sep 2020 13:35:39
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 13:35:39

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-21T06:10:23', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b6015ed7-f65f-4ba2-a743-b434bf6da447'	System	21 Nov 2020 12:10:01
User entered 'No (N)'	System	21 Nov 2020 12:10:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-21T06:10:42', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b6015ed7-f65f-4ba2-a743-b434bf6da447'	System	21 Nov 2020 12:10:01
User entered 'No (N)'	System	21 Nov 2020 12:10:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-21T06:10:47', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b6015ed7-f65f-4ba2-a743-b434bf6da447'	System	21 Nov 2020 12:10:01
User entered '21 Nov 2020 06:10:47'	System	21 Nov 2020 12:10:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-28T05:47:57', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '53fdbea8-c7e1-4317-be07-a0e4371cfa57'	System	28 Nov 2020 11:47:05
User entered 'No (N)'	System	28 Nov 2020 11:47:05

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-28T05:48:06', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '53fdbea8-c7e1-4317-be07-a0e4371cfa57'	System	28 Nov 2020 11:47:05
User entered 'No (N)'	System	28 Nov 2020 11:47:05

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-11-28T05:48:10', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '53fdbea8-c7e1-4317-be07-a0e4371cfa57'	System	28 Nov 2020 11:47:05
User entered '28 Nov 2020 05:48:10'	System	28 Nov 2020 11:47:05

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-05T08:12:35', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8a06bf63-22b2-4b04-aded-e7a896b9378c'	System	05 Dec 2020 14:11:26
User entered 'No (N)'	System	05 Dec 2020 14:11:26

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-05T08:12:44', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8a06bf63-22b2-4b04-aded-e7a896b9378c'	System	05 Dec 2020 14:11:26
User entered 'No (N)'	System	05 Dec 2020 14:11:26

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-05T08:12:47', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8a06bf63-22b2-4b04-aded-e7a896b9378c' User entered '05 Dec 2020 08:12:47'	System	05 Dec 2020 14:11:26
	System	05 Dec 2020 14:11:26

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-12T07:21:01', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '16c601a8-540d-4da3-b4e0-7b9bdf66688d'	System	12 Dec 2020 13:21:45
User entered 'No (N)'	System	12 Dec 2020 13:21:45

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-12T07:21:13', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '16c601a8-540d-4da3-b4e0-7b9bdf66688d'	System	12 Dec 2020 13:21:45
User entered 'No (N)'	System	12 Dec 2020 13:21:45

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-12T07:21:28', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '16c601a8-540d-4da3-b4e0-7b9bdf66688d' User entered '12 Dec 2020 07:21:28'	System	12 Dec 2020 13:21:45
	System	12 Dec 2020 13:21:45

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-19T06:42:03', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3a15a4f9-de11-4529-af65-06d3164b447f'	System	19 Dec 2020 12:42:19
User entered 'No (N)'	System	19 Dec 2020 12:42:19

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-19T06:42:11', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3a15a4f9-de11-4529-af65-06d3164b447f'	System	19 Dec 2020 12:42:19
User entered 'No (N)'	System	19 Dec 2020 12:42:19

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-19T06:42:17', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3a15a4f9-de11-4529-af65-06d3164b447f' User entered '19 Dec 2020 06:42:17'	System	19 Dec 2020 12:42:19
	System	19 Dec 2020 12:42:19

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-26T06:36:14', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8c7abff5-cbf6-4e4f-82ba-e6545455cdb7'	System	26 Dec 2020 12:36:15
User entered 'No (N)'	System	26 Dec 2020 12:36:15

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-26T06:36:26', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8c7abff5-cbf6-4e4f-82ba-e6545455cdb7'	System	26 Dec 2020 12:36:15
User entered 'No (N)'	System	26 Dec 2020 12:36:15

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2020-12-26T06:36:32', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8c7abff5-cbf6-4e4f-82ba-e6545455cdb7'	System	26 Dec 2020 12:36:15
User entered '26 Dec 2020 06:36:32'	System	26 Dec 2020 12:36:15

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-02T07:09:03', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4137d90f-9d99-435a-ad55-a0d044e6310f'	System	02 Jan 2021 13:08:39
User entered 'No (N)'	System	02 Jan 2021 13:08:39

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-02T07:09:07', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4137d90f-9d99-435a-ad55-a0d044e6310f'	System	02 Jan 2021 13:08:39
User entered 'No (N)'	System	02 Jan 2021 13:08:39

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-02T07:09:11', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '4137d90f-9d99-435a-ad55-a0d044e6310f' User entered '02 Jan 2021 07:09:11'	System	02 Jan 2021 13:08:39
	System	02 Jan 2021 13:08:39

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-09T06:20:16', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ba01196d-c1c2-44bf-9cec-c74bf1af52c2'	System	09 Jan 2021 12:19:48
User entered 'No (N)'	System	09 Jan 2021 12:19:48

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-09T06:20:31', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ba01196d-c1c2-44bf-9cec-c74bf1af52c2'	System	09 Jan 2021 12:19:48
User entered 'No (N)'	System	09 Jan 2021 12:19:48

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-09T06:20:37', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'ba01196d-c1c2-44bf-9cec-c74bf1af52c2' User entered '09 Jan 2021 06:20:37'	System	09 Jan 2021 12:19:48
	System	09 Jan 2021 12:19:48

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-16T08:38:51', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f4b89fb3-239c-4bb7-9b53-967732b34ad5'	System	16 Jan 2021 14:37:56
User entered 'No (N)'	System	16 Jan 2021 14:37:56

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-16T08:38:57', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f4b89fb3-239c-4bb7-9b53-967732b34ad5'	System	16 Jan 2021 14:37:56
User entered 'No (N)'	System	16 Jan 2021 14:37:56

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-16T08:39:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f4b89fb3-239c-4bb7-9b53-967732b34ad5'	System	16 Jan 2021 14:37:56
User entered '16 Jan 2021 08:39:00'	System	16 Jan 2021 14:37:56

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-23T06:21:18', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3117b3e9-94d8-4a10-af6b-69aca53fd458'	System	23 Jan 2021 12:20:17
User entered 'No (N)'	System	23 Jan 2021 12:20:17

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-23T06:21:34', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3117b3e9-94d8-4a10-af6b-69aca53fd458'	System	23 Jan 2021 12:20:17
User entered 'No (N)'	System	23 Jan 2021 12:20:17

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-23T06:21:37', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '3117b3e9-94d8-4a10-af6b-69aca53fd458'	System	23 Jan 2021 12:20:17
User entered '23 Jan 2021 06:21:37'	System	23 Jan 2021 12:20:17

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-30T06:24:12', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9a27c60f-be6d-4db0-974e-260c49fda172'	System	30 Jan 2021 12:24:42
User entered 'No (N)'	System	30 Jan 2021 12:24:42

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-30T06:24:23', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9a27c60f-be6d-4db0-974e-260c49fda172'	System	30 Jan 2021 12:24:42
User entered 'No (N)'	System	30 Jan 2021 12:24:42

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-01-30T06:24:35', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '9a27c60f-be6d-4db0-974e-260c49fda172'	System	30 Jan 2021 12:24:42
User entered '30 Jan 2021 06:24:35'	System	30 Jan 2021 12:24:42

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-06T04:55:27', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd679c567-54fe-4717-8bc9-0c7fa1d03bd1'	System	06 Feb 2021 10:55:28
User entered 'No (N)'	System	06 Feb 2021 10:55:28

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-06T04:55:38', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd679c567-54fe-4717-8bc9-0c7fa1d03bd1'	System	06 Feb 2021 10:55:28
User entered 'No (N)'	System	06 Feb 2021 10:55:28

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-06T04:55:41', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'd679c567-54fe-4717-8bc9-0c7fa1d03bd1'	System	06 Feb 2021 10:55:28
User entered '06 Feb 2021 04:55:41'	System	06 Feb 2021 10:55:28

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-13T06:52:15', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e03ab85a-1935-4446-a98b-25c2445c50bf'	System	13 Feb 2021 12:51:59
User entered 'No (N)'	System	13 Feb 2021 12:51:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-13T06:52:25', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e03ab85a-1935-4446-a98b-25c2445c50bf'	System	13 Feb 2021 12:51:59
User entered 'No (N)'	System	13 Feb 2021 12:51:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-13T06:52:29', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e03ab85a-1935-4446-a98b-25c2445c50bf' User entered '13 Feb 2021 06:52:29'	System	13 Feb 2021 12:51:59
	System	13 Feb 2021 12:51:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-20T08:54:37', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '05b8303b-0aee-4a0f-8540-f6401e875dfc'	System	20 Feb 2021 14:53:59
User entered 'No (N)'	System	20 Feb 2021 14:53:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-20T08:54:43', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '05b8303b-0aee-4a0f-8540-f6401e875dfc'	System	20 Feb 2021 14:53:59
User entered 'No (N)'	System	20 Feb 2021 14:53:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-20T08:54:46', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '05b8303b-0aee-4a0f-8540-f6401e875dfc'	System	20 Feb 2021 14:53:59
User entered '20 Feb 2021 08:54:46'	System	20 Feb 2021 14:53:59

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-27T08:35:01-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de8497d1-1048-489b-8402-8103908643dd' User entered 'No (N)'	System	27 Feb 2021 14:34:05

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-27T08:35:06-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de8497d1-1048-489b-8402-8103908643dd' User entered 'No (N)'	System	27 Feb 2021 14:34:05

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-02-27T08:35:09-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'de8497d1-1048-489b-8402-8103908643dd'	System	27 Feb 2021 14:34:05
User entered '27 Feb 2021 08:35:09'	System	27 Feb 2021 14:34:05

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-06T08:05:24-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6f6894fb-68f5-442b-b989-c7c3cda74e61'	System	06 Mar 2021 14:04:17
User entered 'No (N)'	System	06 Mar 2021 14:04:17

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-06T08:05:29-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6f6894fb-68f5-442b-b989-c7c3cda74e61'	System	06 Mar 2021 14:04:17
User entered 'No (N)'	System	06 Mar 2021 14:04:17

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-06T08:05:32-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '6f6894fb-68f5-442b-b989-c7c3cda74e61'	System	06 Mar 2021 14:04:17
User entered '06 Mar 2021 08:05:32'	System	06 Mar 2021 14:04:17

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-13T05:28:42-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f6654761-ce3d-4afe-a350-4c311db182cf' User entered 'No (N)'	System	13 Mar 2021 11:29:21
	System	13 Mar 2021 11:29:21

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-13T05:28:48-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f6654761-ce3d-4afe-a350-4c311db182cf' User entered 'No (N)'	System	13 Mar 2021 11:29:21
	System	13 Mar 2021 11:29:21

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-13T05:28:51-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'f6654761-ce3d-4afe-a350-4c311db182cf' User entered '13 Mar 2021 05:28:51'	System	13 Mar 2021 11:29:21
	System	13 Mar 2021 11:29:21

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-20T00:28:30-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '93b4be3d-038e-4c47-ad64-d0bd5c71d63e' User entered 'No (N)'	System	20 Mar 2021 05:28:52

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-20T00:28:35-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '93b4be3d-038e-4c47-ad64-d0bd5c71d63e'	System	20 Mar 2021 05:28:52
User entered 'No (N)'	System	20 Mar 2021 05:28:52

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-20T00:28:39-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '93b4be3d-038e-4c47-ad64-d0bd5c71d63e' User entered '20 Mar 2021 00:28:39'	System	20 Mar 2021 05:28:52
	System	20 Mar 2021 05:28:52

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-27T09:22:43-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8996919b-a3b5-4edc-b81e-993b585b2f43'	System	27 Mar 2021 14:22:44
User entered 'No (N)'	System	27 Mar 2021 14:22:44

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-27T09:22:48-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8996919b-a3b5-4edc-b81e-993b585b2f43'	System	27 Mar 2021 14:22:44
User entered 'No (N)'	System	27 Mar 2021 14:22:44

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-27T09:22:52-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8996919b-a3b5-4edc-b81e-993b585b2f43'	System	27 Mar 2021 14:22:44
User entered '27 Mar 2021 09:22:52'	System	27 Mar 2021 14:22:44

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-07T12:20:46-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e716cb2e-c074-49be-8c2e-e8c011aee97c'	System	07 Apr 2021 17:24:46
User entered 'Yes (Y)'	System	07 Apr 2021 17:24:46

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-07T12:20:59-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e716cb2e-c074-49be-8c2e-e8c011aee97c'	System	07 Apr 2021 17:24:46
User entered 'No (N)'	System	07 Apr 2021 17:24:46

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-07T12:21:06-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e716cb2e-c074-49be-8c2e-e8c011aee97c'	System	07 Apr 2021 17:24:46
User entered 'No (N)'	System	07 Apr 2021 17:24:46

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-07T12:21:20-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e716cb2e-c074-49be-8c2e-e8c011aee97c'	System	07 Apr 2021 17:24:46
User entered 'Yes (Y)'	System	07 Apr 2021 17:24:46

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-07T12:21:29-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e716cb2e-c074-49be-8c2e-e8c011aee97c'	System	07 Apr 2021 17:24:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 17:24:46

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-07T12:21:32-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'e716cb2e-c074-49be-8c2e-e8c011aee97c'	System	07 Apr 2021 17:24:46
User entered '07 Apr 2021 12:21:32'	System	07 Apr 2021 17:24:46

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-10T10:22:33-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b9c61331-ea15-4794-9541-1d39330920e6'	System	10 Apr 2021 15:22:02
User entered 'No (N)'	System	10 Apr 2021 15:22:02

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-10T10:22:37-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b9c61331-ea15-4794-9541-1d39330920e6'	System	10 Apr 2021 15:22:02
User entered 'No (N)'	System	10 Apr 2021 15:22:02

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-10T10:22:43-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'b9c61331-ea15-4794-9541-1d39330920e6'	System	10 Apr 2021 15:22:02
User entered '10 Apr 2021 10:22:43'	System	10 Apr 2021 15:22:02

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-17T05:14:16-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8ff2b4a8-9f4e-477e-b757-56b7a4251f81'	System	17 Apr 2021 10:14:37
User entered 'Yes (Y)'	System	17 Apr 2021 10:14:37

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-17T05:14:25-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8ff2b4a8-9f4e-477e-b757-56b7a4251f81' User entered 'No (N)'	System	17 Apr 2021 10:14:37

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-17T05:14:33-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8ff2b4a8-9f4e-477e-b757-56b7a4251f81' User entered 'No (N)'	System	17 Apr 2021 10:14:37
	System	17 Apr 2021 10:14:37

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-17T05:14:48-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8ff2b4a8-9f4e-477e-b757-56b7a4251f81'	System	17 Apr 2021 10:14:37
User entered 'Yes (Y)'	System	17 Apr 2021 10:14:37

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-17T05:15:08-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8ff2b4a8-9f4e-477e-b757-56b7a4251f81'	System	17 Apr 2021 10:14:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Apr 2021 10:14:37

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-17T05:15:27-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8ff2b4a8-9f4e-477e-b757-56b7a4251f81'	System	17 Apr 2021 10:14:37
User entered '17 Apr 2021 05:15:27'	System	17 Apr 2021 10:14:37

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-24T07:45:27-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8cb54424-6ecc-4b7e-ba86-5a34935ae35d' User entered 'Yes (Y)'	System	24 Apr 2021 12:45:21
	System	24 Apr 2021 12:45:21

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-24T07:45:35-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8cb54424-6ecc-4b7e-ba86-5a34935ae35d' User entered 'No (N)'	System	24 Apr 2021 12:45:21

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-24T07:45:43-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8cb54424-6ecc-4b7e-ba86-5a34935ae35d' User entered 'No (N)'	System	24 Apr 2021 12:45:21
	System	24 Apr 2021 12:45:21

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-24T07:46:06-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8cb54424-6ecc-4b7e-ba86-5a34935ae35d'	System	24 Apr 2021 12:45:21
User entered 'Yes (Y)'	System	24 Apr 2021 12:45:21

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-24T07:46:24-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8cb54424-6ecc-4b7e-ba86-5a34935ae35d'	System	24 Apr 2021 12:45:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Apr 2021 12:45:21

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-04-24T07:46:28-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '8cb54424-6ecc-4b7e-ba86-5a34935ae35d' User entered '24 Apr 2021 07:46:28'	System	24 Apr 2021 12:45:21
	System	24 Apr 2021 12:45:21

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-05-01T09:21:11-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '10896940-479d-4d63-b7fe-c4961a0abef8'	System	01 May 2021 14:19:50
User entered 'No (N)'	System	01 May 2021 14:19:50

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-05-01T09:21:16-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '10896940-479d-4d63-b7fe-c4961a0abef8'	System	01 May 2021 14:19:50
User entered 'No (N)'	System	01 May 2021 14:19:50

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-05-01T09:21:20-05:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: '10896940-479d-4d63-b7fe-c4961a0abef8'	System	01 May 2021 14:19:50
User entered '01 May 2021 09:21:20'	System	01 May 2021 14:19:50

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 02:46:01

US3572170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:46:01
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 02:46:01

US3572170

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:17:31

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)	25 Apr 2021 18:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-04T13:16:57-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'efe33d33-24f7-4d0c-a029-3e02b8bafdc1'	System	04 Mar 2021 19:16:04
User entered 'No (N)'	System	04 Mar 2021 19:16:04

US3572170

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:17:31

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (623c4141f0ab10ff)', Time: '2021-03-04T13:17:14-06:00', User OID: 'PatientReportedOutcome (US3572170)', ODM File OID: 'efe33d33-24f7-4d0c-a029-3e02b8bafdc1'	System	04 Mar 2021 19:16:04
User entered '04 Mar 2021 13:17:14'	System	04 Mar 2021 19:16:04

US3572170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:17:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:11:53
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	30 Nov 2020 20:44:39

US3572170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:17:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:11:53
User entered '30 Nov 2020'	Martha Bunnell-Pollak (b) (4)	30 Nov 2020 20:44:39

US3572170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:17:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:11:53
User entered 'Contact Made (CONTACT MADE)'	Martha Bunnell-Pollak (b) (4)	30 Nov 2020 20:44:39

US3572170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:17:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:11:53
User entered empty.	Martha Bunnell-Pollak (b) (4)	30 Nov 2020 20:44:39

US3572170

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:17:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:12:40
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	30 Nov 2020 20:44:43

US3572170

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:41
User entered 'l'	System	30 Nov 2020 20:44:43

US3572170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:02:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 21JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:05:48
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 21JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'data recorded now for this sample' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 23:48:23
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 21JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:59:52
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	06 Jan 2021 16:45:17

US3572170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:02:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '6 Jan 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Jan 2021 16:45:17

US3572170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:02:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Jan 2021 16:45:17

US3572170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:02:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Jan 2021 16:45:17

US3572170

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:02:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Jan 2021 16:45:20

US3572170

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
User entered 'l'	System	06 Jan 2021 16:45:20

US3572170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:42:37
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	02 Feb 2021 16:20:14

US3572170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:42:37
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 15:03:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'sample data for labs collected 21Jan for PDV have been entered into EDC' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 00:02:43
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:58:17
User entered '2 Feb 2021'	Martha Bunnell-Pollak (b) (4)	02 Feb 2021 16:20:14

US3572170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:42:37
User entered 'Contact Made (CONTACT MADE)'	Martha Bunnell-Pollak (b) (4)	02 Feb 2021 16:20:14

US3572170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:42:37
User entered empty.	Martha Bunnell-Pollak (b) (4)	02 Feb 2021 16:20:14

US3572170

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:42:42
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	02 Feb 2021 16:20:20

US3572170

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
User entered 'l'	System	02 Feb 2021 16:20:20

US3572170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:41:10
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:33:03

US3572170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:41:10
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '4 Mar 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:33:03

US3572170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:41:10
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:33:03

US3572170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:41:10
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:33:03

US3572170

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:41:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:33:12

US3572170

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:36
User entered 'l'	System	04 Mar 2021 17:33:12

US3572170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:56:36

US3572170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '6 Apr 2021'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:56:36

US3572170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:56:36

US3572170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	14 Apr 2021 22:56:36

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '6 Apr 2021'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '14:46' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:58:34
User entered '13:30'	(b) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User entered '6 Apr 2021 14:46'	System	14 Apr 2021 22:58:34
User entered '6 Apr 2021 13:30'	System	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '97.7' F	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'TEMPORAL'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '53'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '18'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '135'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '74'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Apr 2021 22:57:49

US3572170

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:58:00

US3572170

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '6 Apr 2021'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:58:00

US3572170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:58:11

US3572170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '6 Apr 2021'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:58:11

US3572170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '13:30'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:58:11

US3572170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User entered '6 Apr 2021 13:30'	System	14 Apr 2021 22:58:11

US3572170

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:58:15

US3572170

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Apr 2021 22:58:15

US3572170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:33:41

US3572170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered '3 May 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:33:41

US3572170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:33:41

US3572170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:33:41

US3572170

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:33:45

US3572170

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 17:33:45

US3572170

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:24:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:48:46

US3572170

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:24:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:48:46

US3572170

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[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 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:24:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:48:46

US3572170

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 23:48:46

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 02:20:38
User closed query 'Was subject consented on 06 Jan 2021 ICF at this visit. Not present in EMR source. Please advise' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 02:20:20
Query 'Was subject consented on 06 Jan 2021 ICF at this visit. Not present in EMR source. Please advise' answered with 'subject consented on 21JAN21 not on 06Jan21. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:04:04
User opened query 'Was subject consented on 06 Jan 2021 ICF at this visit. Not present in EMR source. Please advise' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 18:36:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '21 Jan 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:49:21

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:33:30

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:27:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:49:21

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:33:30

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:27:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:49:21

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:27:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:49:21

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:27:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:49:21

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:27:33
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:49:21

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:27:43
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:49:21

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'I'	System	22 Feb 2021 23:49:21

US3572170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'I'	System	22 Feb 2021 23:49:21

US3572170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered empty.	System	22 Feb 2021 23:51:33
DataPoint set to visible.	System	22 Feb 2021 23:49:21

US3572170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered empty.	System	22 Feb 2021 23:51:33
DataPoint set to visible.	System	22 Feb 2021 23:49:21

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '21 Jan 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '17:00'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered '21 Jan 2021 17:00'	System	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:00:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:00:35
User entered '97.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:00:35
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 00:00:35
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 00:00:35
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:00:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:00:35
User entered '49' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:00:35
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'bpm'	System	23 Feb 2021 00:00:35
User entered empty.	System	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:00:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:00:35
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:00:35
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'breaths/min'	System	23 Feb 2021 00:00:35
User entered empty.	System	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:00:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:00:35
User entered '149' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:00:35
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'mmHg'	System	23 Feb 2021 00:00:35
User entered empty.	System	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:00:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:00:35
User entered '87' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:00:35
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'mmHg'	System	23 Feb 2021 00:00:35
User entered empty.	System	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered empty.	System	22 Feb 2021 23:51:33
DataPoint set to visible.	System	22 Feb 2021 23:49:21

US3572170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Feb 2021 23:51:33

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:51:33

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '21 Jan 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:51:33

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '20:25'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:33

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered '21 Jan 2021 20:25'	System	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:01:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:01:36
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:01:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 00:01:36
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 00:01:36
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:01:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:01:36
User entered '49' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:01:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'bpm'	System	23 Feb 2021 00:01:36
User entered empty.	System	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:01:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:01:36
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:01:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'breaths/min'	System	23 Feb 2021 00:01:36
User entered empty.	System	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:01:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:01:36
User entered '140' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:01:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'mmHg'	System	23 Feb 2021 00:01:36
User entered empty.	System	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:02:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:01:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 00:01:36
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:01:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:51:33
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:51:33

US3572170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'mmHg'	System	23 Feb 2021 00:01:36
User entered empty.	System	22 Feb 2021 23:51:33

US3572170

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:59:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:39

US3572170

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:59:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:51:39

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:52:01

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:52:01

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered empty.	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:52:01

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'mRNA-1273'	System	22 Feb 2021 23:52:01
DataPoint set to visible.	System	22 Feb 2021 23:49:21

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:52:01

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '19:55'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:52:01

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered '21 Jan 2021 19:55'	System	22 Feb 2021 23:52:01

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:52:01

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:55:35
User entered 'ONCE'	System	22 Feb 2021 23:52:01

US3572170

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered 'INTRAMUSCULAR'	System	22 Feb 2021 23:52:01

US3572170

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:23:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:50:16

US3572170

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:23:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:50:16

US3572170

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:23:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '17:56'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:50:16

US3572170

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:51
User entered '21 Jan 2021 17:56'	System	22 Feb 2021 23:50:16

US3572170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:41:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:50:39

US3572170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:41:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '21 Jan 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:50:39

US3572170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:41:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '17:54'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:50:39

US3572170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered '21 Jan 2021 17:54'	System	22 Feb 2021 23:50:39

US3572170

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

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:54:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:52:06

US3572170

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

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:13:19
User entered 'I'	System	22 Feb 2021 23:52:06

US3572170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:53:19

US3572170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '28 Jan 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:53:19

US3572170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:53:19

US3572170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:53:19

US3572170

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:15:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:53:24

US3572170

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:19
User entered 'l'	System	22 Feb 2021 23:53:24

US3572170

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:19
User entered 'I'	System	22 Feb 2021 23:53:24
DataPoint set to visible.	System	22 Feb 2021 23:53:24

US3572170

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:30:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:55:47

US3572170

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:30:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:55:47

US3572170

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[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 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:30:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:55:47

US3572170

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'OLD29'	System	22 Feb 2021 23:55:47

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '17:30'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered '19 Feb 2021 17:30'	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User signature succeeded.	Milton Haber (b) (4)	20 Apr 2021 05:40:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 02:49:20
User closed query 'Temp recorded as 97.9, per source. Please review and confirm.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 02:49:07
Query 'Temp recorded as 97.9, per source. Please review and confirm.' answered with 'reviewed and confirmed' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:07:55
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:07:36
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 21:07:36
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:07:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User opened query 'Temp recorded as 97.9, per source. Please review and confirm.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:34:46
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:10
User entered '97.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:10
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	22 Feb 2021 23:57:10
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	22 Feb 2021 23:57:10
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:10
User entered '53' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:10
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'bpm'	System	22 Feb 2021 23:57:10
User entered empty.	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:10
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:10
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'breaths/min'	System	22 Feb 2021 23:57:10
User entered empty.	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:10
User entered '124' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:10
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mmHg'	System	22 Feb 2021 23:57:10
User entered empty.	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:10
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:10
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mmHg'	System	22 Feb 2021 23:57:10
User entered empty.	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '18:05'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered '19 Feb 2021 18:05'	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:46
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:46
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	22 Feb 2021 23:57:46
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	22 Feb 2021 23:57:46
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:46
User entered '51' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:46
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'bpm'	System	22 Feb 2021 23:57:46
User entered empty.	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:46
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:46
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'breaths/min'	System	22 Feb 2021 23:57:46
User entered empty.	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:46
User entered '135' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:46
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mmHg'	System	22 Feb 2021 23:57:46
User entered empty.	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:57:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Feb 2021 23:57:46
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 23:57:46
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Feb 2021 23:56:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mmHg'	System	22 Feb 2021 23:57:46
User entered empty.	System	22 Feb 2021 23:56:25

US3572170

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:31:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:58:08

US3572170

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:31:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:58:08

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:36:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:58:30

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:36:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:58:30

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:36:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered empty.	(b) (4) (u) (4), (b) (6)	22 Feb 2021 23:58:30

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'mRNA-1273'	System	22 Feb 2021 23:58:30
DataPoint set to visible.	System	22 Feb 2021 23:53:24

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:36:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:58:30

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:36:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '18:05'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:58:30

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered '19 Feb 2021 18:05'	System	22 Feb 2021 23:58:30

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:36:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:58:30

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:36:25
User entered 'ONCE'	System	22 Feb 2021 23:58:30

US3572170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'INTRAMUSCULAR'	System	22 Feb 2021 23:58:30

US3572170

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:36:43
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:58:35

US3572170

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:16
User entered 'l'	System	22 Feb 2021 23:58:35

US3572170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:43
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	26 Feb 2021 18:12:19

US3572170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:48
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered '26 Feb 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	26 Feb 2021 18:12:19

US3572170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:48
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	26 Feb 2021 18:12:19

US3572170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:48
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	26 Feb 2021 18:12:19

US3572170

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:56
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	26 Feb 2021 18:12:23

US3572170

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:29
User entered 'l'	System	26 Feb 2021 18:12:23

US3572170

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:17:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:03:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)' reason for change: New Information	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:33:24
User entered 'No (N)'	Martha Bunnell-Pollak (b) (4)	17 Sep 2020 16:36:13

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:04:43
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 09:55:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 09:55:33
Data point term sent to Coder	System	04 Mar 2021 17:35:53
User entered 'S/P Fall'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:04:45
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'No (N)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:04:49
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'No (N)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:04:53
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'No (N)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:04:55
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '17 Feb 2021'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:01
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered empty.	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
User entered empty.	System	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:03
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'No (N)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '17 Feb 2021'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:13
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered empty.	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
User entered empty.	System	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:22
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:25
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'No (N)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:47
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '0'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:49
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '0'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:52
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '0'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:55
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered empty.	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:05:59
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered empty.	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:02
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered empty.	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered empty.	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:09
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '0'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:13
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '0'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:17
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '0'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:20
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'Not Related (NOT RELATED)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'Not Related (NOT RELATED)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:25
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'None (NONE)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:29
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'l'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:32
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '0'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:35
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered '0'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:50
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:53
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'Subject continues to have chronic neck pain.'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:07:10
User closed query 'Per DM CLR: Narrative indicates that the subject has Injured Neck. However, there is no recorded AE that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:07:41
Query 'Per DM CLR: Narrative indicates that the subject has Injured Neck. However, there is no recorded AE that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'AE Log has been updated' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:44:02
User opened query 'Per DM CLR: Narrative indicates that the subject has Injured Neck. However, there is no recorded AE that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:49:55
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:05
User entered 'Subject states he slipped on some ice on 2/17/2021 and injured his neck. He has a history of back injury from several years ago and he feels since his fall, he is experiencing chronic pain in cervical spine area. He is not taking any new medications to treat pain.'	Martha Bunnell-Pollak (b) (4)	04 Mar 2021 17:34:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
User entered '0'	System	04 Mar 2021 17:34:56

US3572170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46
User entered '0'	System	04 Mar 2021 17:34:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Neck injury, LLT: Neck injury - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 22:25:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 22:25:57
Data point term sent to Coder	System	07 Apr 2021 15:44:06
User entered 'Neck Injury due to fall'	(b) (4), (b) (6)	07 Apr 2021 15:43:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '17 Feb 2021'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered empty.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
User entered empty.	System	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	System	07 Apr 2021 15:43:41
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 15:43:41
User entered 'Yes (Y)'	System	07 Apr 2021 15:43:33
	(b) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '3 Mar 2021'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered empty.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
User entered empty.	System	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '0'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '0'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '0'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered empty.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered empty.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered empty.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered empty.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '0'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '0'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '0'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'None (NONE)'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'l'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '0'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered '0'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered empty.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:08:39
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:30
User entered empty.	(b) (4) (u) (4), (b) (6)	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
User entered '0'	System	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50
User entered '0'	System	07 Apr 2021 15:43:33

US3572170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:27:50

US3572170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:01:57
User entered	System	14 Apr 2021 17:01:51
'USA-US091-2021-mRNA-1273-P301000018'		
User entered 'New'	(b) (4), (b) (6)	14 Apr 2021 17:01:51

US3572170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 17:11:46
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:54:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	Coder Import (b) (4)	26 Apr 2021 20:46:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	26 Apr 2021 20:46:57
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:46:39
Data point term sent to Coder	System	26 Apr 2021 20:46:05
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:34
Coding entries removed.	(b) (4), (b) (6)	26 Apr 2021 20:45:34
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 20:45:34
User entered 'GASTROESOPHAGEAL REFLUX DISEASE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 20:45:34
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:04:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 21:47:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 21:47:43
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal tenderness, LLT: Tenderness epigastric - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:14:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:14:35
Data point term sent to Coder	System	13 Apr 2021 19:19:36
User entered 'Epigastric Tenderness (GERD)'	Maria Candelario (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'No (N)'	Maria Candelario (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered '29 Mar 2021'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered empty.	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event outcome for epigastric tenderness (GERD), when available. Please keep query open until resolution is achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:05:10
User opened query 'PV Query: Please provide the event outcome for epigastric tenderness (GERD), when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:03:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'Yes (Y)'	Maria Candelario (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: For the event of epigastric tenderness (GERD), please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 12:13:49
Query 'PV Query: For the event of epigastric tenderness (GERD), 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 'Ongoing is answered yes	(b) (4), (b) (6)	29 Apr 2021 19:58:05
' (Site from Safety).		
User opened query 'PV Query: For the event of epigastric tenderness (GERD), please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:27:57
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	13 Apr 2021 19:19:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered empty.	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: For the event of epigastric tenderness (GERD), please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:27:45
User opened query 'PV Query: For the event of epigastric tenderness (GERD), please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:04:39
User entered empty.	System	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered 'Grade 4 (Grade 4)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'No ICU Admission' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 03:04:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'No ICU Admission' (Site from System).	Maria Candelario (b) (4)	13 Apr 2021 19:24:40
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Apr 2021 19:19:02
User entered 'I'	Maria Candelario (b) (4)	13 Apr 2021 19:19:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered '12 Apr 2021'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:54:00
DataPoint Un-verified.	Maria Candelario (b) (4)	28 Apr 2021 15:17:48
	(b) (4)	
Signature has been broken.	Maria Candelario (b) (4)	28 Apr 2021 15:17:48
	(b) (4)	
User entered '14 Apr 2021' reason for change: Data Entry Error	Maria Candelario (b) (4)	28 Apr 2021 15:17:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 19:19:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered empty.	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered 'Not Related (NOT RELATED)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered 'Not Related (NOT RELATED)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered 'Not Applicable (NOT APPLICABLE)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered 'l'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
DataPoint Verified.	(b) (4)	
	(u) (4), (b) (6)	27 Apr 2021 17:11:38
User closed query 'PV Query: Please provide the event outcome for epigastric tenderness (GERD), when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:54:36
Query 'PV Query: Please provide the event outcome for epigastric tenderness (GERD), when available. Please keep query open until resolution is achieved.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:51:54
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 20:49:40
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 20:49:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 20:49:40
User opened query 'PV Query: Please provide the event outcome for epigastric tenderness (GERD), when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:05:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(u) (4), (b) (6)	15 Apr 2021 15:02:42
Query 'Data is required. Please complete.' answered with 'The subject is currently in the hospital' (Site from System).	Maria Candelario (b) (4)	13 Apr 2021 19:19:56
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Apr 2021 19:19:02
	Maria Candelario (b) (4)	13 Apr 2021 19:19:02
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:14:36
User entered empty.	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 11:54:30
User closed query 'PV Query: Please send hospitalization medical records. Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 11:54:15
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 'updated' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 20:02:59
Query 'PV Query: Please send hospitalization medical records. Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Records sent' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 20:02:45
User closed query 'PV Query: Please confirm if the subject was hospitalized with myocardial infarction (MI). If so, please consider adding MI as an SAE.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 17:10:33
Query 'PV Query: Please confirm if the subject was hospitalized with myocardial infarction (MI). If so, please consider adding MI as an SAE.' answered with 'Discharge summary was received, NSTEMI will be reported as separate SAE. ' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 15:17:13
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:54:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:31

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'AS PER MEDICAL RECORDS PROVIDED NO COVID TEST PERFORMED' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 21:19:26
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:03:47
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)	22 Apr 2021 13:03:32
User opened query 'PV Query: Please send hospitalization medical records. Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:03:16
User opened query 'PV Query: Please confirm if the subject was hospitalized with myocardial infarction (MI). If so, please consider adding MI as an SAE.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:02:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:38:56
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'PI reported today (4/13) that subject had an MI and was hospitalized and underwent angioplasty. He is currently in the hospital; medical records have been requested.'	Maria Candelario (b) (4)	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 19:19:02

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Folder: Adverse Events

Form: Adverse Events (4)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	29 Apr 2021 15:47:41
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	29 Apr 2021 13:17:52
User entered 'USA-US091-2021-mRNA-1273-P301000018'	(b) (4), (b) (6)	29 Apr 2021 13:17:31

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non STEMI - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 19:55:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 19:55:18
Data point term sent to Coder	System	28 Apr 2021 19:48:42
User entered 'NSTEMI'	Maria Candelario (b) (4)	28 Apr 2021 19:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered '10 Apr 2021'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered empty.	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User entered '10 Apr 2021'	(b) (4) Maria Candelario (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered empty.	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 19:55:28
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	System	28 Apr 2021 19:55:28
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	28 Apr 2021 19:55:28
User entered empty.	(b) (4)	
	System	28 Apr 2021 19:47:41
	Maria Candelario (b) (4)	28 Apr 2021 19:47:41
	(b) (4)	

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	
	System	28 Apr 2021 19:55:28
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Apr 2021 19:47:41
User entered 'Yes (Y)'	Maria Candelario (b) (4)	28 Apr 2021 19:47:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	28 Apr 2021 19:55:28
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	28 Apr 2021 19:55:28
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:55:28
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	28 Apr 2021 19:47:41
User entered '0'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User entered '10 Apr 2021'	(b) (4) Maria Candelario (b) (4)	28 Apr 2021 19:47:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User entered '14 Apr 2021'	(b) (4) Maria Candelario (b) (4)	28 Apr 2021 19:47:41
	(b) (4)	

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered empty.	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered '0'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 19:55:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	28 Apr 2021 19:55:28
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	28 Apr 2021 19:55:28
User entered empty.	(b) (4)	
	System	28 Apr 2021 19:47:41
	Maria Candelario (b) (4)	28 Apr 2021 19:47:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'Not Related (NOT RELATED)'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'Not Applicable (NOT APPLICABLE)'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Apr 2021 19:55:28
User entered '0'	System	28 Apr 2021 19:47:41
	Maria Candelario (b) (4)	28 Apr 2021 19:47:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:55:28
User entered '0'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Maria Candelario (b) (4)	28 Apr 2021 19:55:28
User entered '0'	(b) (4)	
	Maria Candelario (b) (4)	28 Apr 2021 19:47:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User entered empty.	(b) (4) Maria Candelario (b) (4)	28 Apr 2021 19:47:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:55:00
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'Subject having gradual onset of chest pain described as chest tightness 1 hr prior to admission. No Associated symptoms such as nausea, vomiting or diaphoresis. subject had bouts of shortness of breath on exertion. ECG revealed nonspecific ST changes, in January 2020 the subject underwent a stress test which revealed myocardial perfusion be normal with no evidence of reversible Ischemia or fixed the left ventricular diastolic systolic function was normal without evidence of regional wall motion, the subject has a history of atrial fibrillation proximal to which the subject been on Flecainide.'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 19:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Apr 2021 19:47:41

US3572170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 19:47:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:17:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:09:48
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:34:04

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:43:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:43:44
Data point term sent to Coder	System	29 Oct 2020 19:42:38
User entered 'Glimepiride' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 19:42:11
User entered 'GLIMEPERIDE'	(b) (4), (b) (6)	29 Oct 2020 19:41:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'DIABETES MELLITUS II'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '4'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '0'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 19:41:41

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:00:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:00:45
Data point term sent to Coder	System	29 Oct 2020 19:44:46
User entered 'Levemir'	(b) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'DIABETES MELLITUS II'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '6'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Other (OTHER)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'UNITS'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'as needed (PRN)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'UN UNK 2018'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '0'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	29 Oct 2020 19:44:33
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	29 Oct 2020 19:44:33
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	29 Oct 2020 19:44:22
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 19:44:22

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:50:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:50:44
Data point term sent to Coder	System	29 Oct 2020 19:49:58
User entered 'Propranolol'	(b) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'ATRIAL FIBRILLATION'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '40'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'UN UNK 1990'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '0'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 19:49:21

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
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)	29 Oct 2020 20:06:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:06:43
Data point term sent to Coder	System	29 Oct 2020 19:52:00
Data point term sent to Coder	System	29 Oct 2020 19:50:59
User entered 'LOSARTAN'	(b) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 19:51:01
User entered 'HYPERTENSION' reason for change: Data Entry Error	System	29 Oct 2020 19:51:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 19:50:50
User entered empty.	System	29 Oct 2020 19:50:50
	(b) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '50'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '0'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 19:50:50

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: BRIMONIDINE TARTRATE;TIMOLOL MALEATE, PRODUCTSYNONYM: COMBIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 06:27:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 06:27:58
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	15 Feb 2021 06:27:27 15 Feb 2021 06:26:29
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: BRIMONIDINE TARTRATE;TIMOLOL MALEATE, PRODUCTSYNONYM: COMBIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:23:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:23:45
Data point term sent to Coder User entered 'COMBIGAN'	System (b) (4), (b) (6)	29 Oct 2020 20:08:34 29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 20:08:32
User entered 'No (N)' reason for change: Data Entry Error	System	29 Oct 2020 20:08:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 20:08:27
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'GLAUCOMA'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'l'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'DROP'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:05:09
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:26:37
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 06:26:29
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 16:21:10
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Ophthalmic' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	15 Feb 2021 06:26:29
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '0'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 20:08:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 11:45:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 11:45:58
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	16 Feb 2021 15:39:54 16 Feb 2021 15:39:45
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:27:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:27:43
Data point term sent to Coder User entered 'Latanoprost'	System (b) (4), (b) (6)	29 Oct 2020 20:10:37 29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 20:10:08
User entered 'No (N)' reason for change: Data Entry Error	System	29 Oct 2020 20:10:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 20:10:03
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'GLAUCOMA'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'l'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'DROP'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:40:24
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'as per query resolution ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 15:40:21
User entered 'Other (OTHER)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Feb 2021 15:39:45
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 16:25:37
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'ophthalmic route' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:39:45
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '0'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 20:10:03

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: URINARY CONCREMENT SOLVENTS, PRODUCT: POTASSIUM CITRATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Mar 2021 12:03:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Mar 2021 12:03:31
Data point term sent to Coder	System	25 Feb 2021 04:52:18
Data point term sent to Coder	System	25 Feb 2021 04:51:18
Data point term sent to Coder	System	16 Feb 2021 23:03:12
User entered 'POTASSIUM CITRATE extended release (SUPPLEMENT)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	16 Feb 2021 23:03:02
Data point term sent to Coder	System	16 Feb 2021 20:37:39
Coding entries removed.	(b) (4), (b) (6)	16 Feb 2021 20:36:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CITRATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 05:38:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 05:38:49
Data point term sent to Coder	System	29 Oct 2020 20:13:46
User entered 'POTASSIUM CITRATE (SUPPLEMENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:13:24
User entered 'POTASSIUM CITRATE'	(b) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 20:13:11
User entered 'Yes (Y)' reason for change: Data Entry Error	System	29 Oct 2020 20:13:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 20:13:06
User entered empty.	System	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Per response, if con med taken prophylactically please update indication to reflect this, or else clarify indication.' (Site from CRA).	(b) (4)	
Query 'Per response, if con med taken prophylactically please update indication to reflect this, or else clarify indication.' answered with	(b) (4), (b) (6)	28 Feb 2021 18:00:23
'updated' (Site from CRA).		
Query 'Per response, if con med taken prophylactically please update indication to reflect this, or else clarify indication.' answered with	(b) (4), (b) (6)	25 Feb 2021 04:52:10
'updated' (Site from CRA).		
User entered 'RENAL CALCULI PREVENTION Supplement' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 04:52:02
User entered 'RENAL CALCULI prevention' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 04:50:57
User opened query 'Per response, if con med taken prophylactically please update indication to reflect this, or else clarify indication.' (Site from CRA).	(b) (4), (b) (6)	21 Feb 2021 00:24:42
User closed query 'Per source, should med hx be updated in relation to this indication? Or is this prophylactic? Please review and reconcile data.' (Site from CRA).	(b) (4), (b) (6)	21 Feb 2021 00:24:42
User closed query 'Per DM CLR: Please review indication to record actual condition this medication was used to prevent as it cannot be verified as recorded. Update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:13:28
Query 'Per DM CLR: Please review indication to record actual condition this medication was used to prevent as it cannot be verified as recorded. Update as appropriate, otherwise clarify.' answered with	(b) (4), (b) (6)	16 Feb 2021 20:37:06
'updated and reconciled per source' (Site from DM).		
User entered 'renal calculi' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 20:36:45
Query 'Per source, should med hx be updated in relation to this indication? Or is this prophylactic? Please review and reconcile data.' answered with 'Per source, it appears this medication is being taken to prevent this indication.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 20:36:15

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review indication to record actual condition this medication was used to prevent as it cannot be verified as recorded. Update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 16:28:40
User opened query 'Per source, should med hx be updated in relation to this indication? Or is this prophylactic? Please review and reconcile data.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:40:20
User entered 'RENAL CANDIOLI'	(b) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Per DM CLR: Please review dose as there are two doses indicated. However, medication is a single dose drug. Either update Medication or update dose. Update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:52:32
Query 'Per DM CLR: Please review dose as there are two doses indicated. However, medication is a single dose drug. Either update Medication or update dose. Update accordingly.' answered with 'dose updated' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:35:35
User entered '540' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 00:35:25
User opened query 'Per DM CLR: Please review dose as there are two doses indicated. However, medication is a single dose drug. Either update Medication or update dose. Update accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:56:54
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 03:10:34
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Pt contacted for dosage clarification. Dose updated.' (Site from DM).	Alisha Lutat (b) (4)	16 Feb 2021 23:03:22
User entered '15 / 1620' reason for change: Data Entry Error	Alisha Lutat (b) (4)	16 Feb 2021 23:03:02
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 16:28:06
User entered '18'	(b) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'mg (mg)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	16 Feb 2021 23:03:02
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 20:01:39
User entered 'Other (OTHER)'	(b) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User closed query 'Per CDM: The dose unit other specify mentioned as MCG(micrograms) is one of the listed choices of the dose unit (ug). Kindly, update the data field and keep the other specify as blank' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:03:58
Query 'Per CDM: The dose unit other specify mentioned as MCG(micrograms) is one of the listed choices of the dose unit (ug). Kindly, update the data field and keep the other specify as blank' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 20:01:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 20:01:39
User opened query 'Per CDM: The dose unit other specify mentioned as MCG(micrograms) is one of the listed choices of the dose unit (ug). Kindly, update the data field and keep the other specify as blank' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:57:55
User entered 'MCG'	(b) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '0'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 20:13:06

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:53:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:53:46
Data point term sent to Coder	System	29 Oct 2020 20:52:51
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'HYPERLIPIDEMIA'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '40'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'UN UNK 2015'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered '0'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered empty.	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:32
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 20:52:38

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 18:04:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:04:19
Data point term sent to Coder	System	03 May 2021 17:36:05
User entered 'Amiodarone'	Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Antiarrhythmic'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered '100'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'mg (mg)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	03 May 2021 17:35:46
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	03 May 2021 17:35:27
User entered 'twice daily (BID)'	Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
	(b) (4)	
User entered empty; reason for change Data Entry Error	Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:46
User entered 'Subject takes 1/2 of 200MG tab BID'	Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Oral (ORAL)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered '15 Apr 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 17:35:27

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 17:38:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 17:38:16
Data point term sent to Coder	System	03 May 2021 17:37:07
User entered 'Plavix'	Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Blood thinner'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered '75'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'mg (mg)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'once daily (QD)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Oral (ORAL)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered '15 Apr 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 22:01:23
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 17:36:33

US3572170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 17:36:33

US3572170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:17:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:53:21
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
DataPoint Un-verified.	(b) (4)	
	Maria Candelario (b) (4)	28 Apr 2021 20:30:07
Signature has been broken.	(b) (4)	
	Maria Candelario (b) (4)	28 Apr 2021 20:30:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Maria Candelario (b) (4)	28 Apr 2021 20:30:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:15:48
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:40:50
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:36:25

US3572170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:53:28
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User entered '11 Apr 2021'	(b) (4) Maria Candelario (b) (4)	28 Apr 2021 20:34:15
	(b) (4)	

US3572170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:53:28
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'Cardiac Catheterization'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 20:34:15

US3572170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:53:28
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered 'Adverse Event (AE)'	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 20:34:15

US3572170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:53:28
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 22:40:36
User entered empty.	Maria Candelario (b) (4) (b) (4)	28 Apr 2021 20:34:15

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:21
User entered 'USA-US091-2021-MRNA-1273-P301000018'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Milton'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Haber'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '2344 Laguna Del Mar, Suite 201'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Laredo'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'TX'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '78041'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'US'	(b) (4) System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 12:14:20
User entered '4'	System	29 Apr 2021 13:18:41
User entered '3'	System	28 Apr 2021 17:09:41
User entered '2'	System	27 Apr 2021 13:55:28
User entered '1'	System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:21
User entered 'USA-US091-2021-MRNA-1273-P301000018'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Milton'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Haber'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '2344 Laguna Del Mar, Suite 201'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Laredo'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'TX'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '78041'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'US'	(b) (4) System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 12:14:20
User entered '4'	System	29 Apr 2021 13:18:41
User entered '3'	System	28 Apr 2021 17:09:41
User entered '2'	System	27 Apr 2021 13:55:28
User entered '1'	System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:17:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered '14/Apr/2021 13:02'	(b) (4) System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:17:31

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)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'l'	(b) (4) (u) (*), (b) (6)	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:21
User entered 'USA-US091-2021-MRNA-1273-P301000018'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Milton'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Haber'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '2344 Laguna Del Mar, Suite 201'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Laredo'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'TX'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '78041'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'US'	(b) (4) System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 12:14:20
User entered '4'	System	29 Apr 2021 13:18:41
User entered '3'	System	28 Apr 2021 17:09:41
User entered '2'	System	27 Apr 2021 13:55:28
User entered '1'	System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:17:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 17:09:56
User entered '27/Apr/2021 09:55'	System	27 Apr 2021 13:55:28

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:17:31

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)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:09:56
User entered 'l'	(b) (4), (b) (6)	27 Apr 2021 13:55:28

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:21
User entered 'USA-US091-2021-MRNA-1273-P301000018'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Milton'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Haber'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '2344 Laguna Del Mar, Suite 201'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Laredo'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'TX'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '78041'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'US'	(b) (4) System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 12:14:20
User entered '4'	System	29 Apr 2021 13:18:41
User entered '3'	System	28 Apr 2021 17:09:41
User entered '2'	System	27 Apr 2021 13:55:28
User entered '1'	System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:17:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:54:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User entered '28/Apr/2021 10:09'	(b) (4) System	28 Apr 2021 17:09:41

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:17:31

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)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:54:00
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:36
User entered 'l'	(b) (4) (u) (4), (b) (6)	28 Apr 2021 17:09:41

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:21
User entered 'USA-US091-2021-MRNA-1273-P301000018'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Milton'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Haber'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '2344 Laguna Del Mar, Suite 201'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Laredo'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'TX'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '78041'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'US'	(b) (4) System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 12:14:20
User entered '4'	System	29 Apr 2021 13:18:41
User entered '3'	System	28 Apr 2021 17:09:41
User entered '2'	System	27 Apr 2021 13:55:28
User entered '1'	System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:17:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:54:00
User signature succeeded.	Milton Haber (b) (4)	29 Apr 2021 15:47:41
User entered '29/Apr/2021 06:18'	(b) (4) System	29 Apr 2021 13:18:41

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:17:31

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)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:54:00
User signature succeeded.	Milton Haber (b) (4)	29 Apr 2021 15:47:41
User entered 'l'	(b) (4) (u) (4), (b) (6)	29 Apr 2021 13:18:41

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:21
User entered 'USA-US091-2021-MRNA-1273-P301000018'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Yes (Y)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'No (N)'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Milton'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Haber'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '2344 Laguna Del Mar, Suite 201'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'Laredo'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered 'TX'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:24
User entered '78041'	System	14 Apr 2021 17:01:51

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 12:14:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:30
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:36
User entered 'US'	(b) (4) System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 12:14:20
User entered '4'	System	29 Apr 2021 13:18:41
User entered '3'	System	28 Apr 2021 17:09:41
User entered '2'	System	27 Apr 2021 13:55:28
User entered '1'	System	14 Apr 2021 17:02:38

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:17:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	30 Apr 2021 16:37:42
User entered '30/Apr/2021 08:14'	(b) (4) System	30 Apr 2021 12:14:20

US3572170

Folder: SAE USA-US091-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:17:31

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)
User signature succeeded.	Milton Haber (b) (4)	30 Apr 2021 16:37:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:14:30
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 12:14:20