

US3682040 (Prod: UCLA Vine Street Clinic - (CRS))

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:04:14

All time stamps listed in this document are displayed in GMT

US3682040

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

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Participant ID

US3682040

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

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US3682040

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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) 20 Apr 2021 18:41:52

Generated On: 11 Aug 2021 23:04:14

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	48
Age Units	YEARS
Age (Derived)	49
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	False
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	True
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Date of Informed Consent ( <i>dd MMM yyyy</i> )	1 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) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Condition	LBP, DISC HERNIATION, L4 & L5
Start date (dd MMM yyyy)	1 SEP 2015
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)	SEP 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Condition	VARICELLA ZOSTER
Start date (dd MMM yyyy)	UN AUG 2020
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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:35 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 09:35
Height ( <i>xxx.x</i> )	168 cm
Weight ( <i>xxx.x</i> )	84 kg
BMI ( <i>xxx.x</i> )	29.76190 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:12:03

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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 ☒

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**Specify**

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**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) 19 Feb 2021 23:12:03

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110472

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) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

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) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

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)	01 SEP 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:35
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

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)	1 SEP 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:28
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 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) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 10:55 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 10:55

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 SEP 2020

Collection time (00:00-23:59)

10:21 (24 HR)

Collection date and time (derived)

01 SEP 2020 10:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:03:45

Generated On: 11 Aug 2021 23:04:14

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:18	01 SEP 2020 10:18
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:03:45

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

**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

01 SEP 2020 11:29

PC Open Date & Time

01 SEP 2020 11:15

PC Close Date & Time

01 SEP 2020 13:45

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

**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	01 SEP 2020 14:47
PC Open Date & Time	01 SEP 2020 14:40
PC Close Date & Time	02 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:04:14

**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

98.3 °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

02 SEP 2020 16:54

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:04:14

**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

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:04:14

**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

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:04:14

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**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

97.3 °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

06 SEP 2020 15:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:04:14

**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

07 SEP 2020 12:00

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

**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

01 SEP 2020 11:30

PC Open Date & Time

01 SEP 2020 11:15

PC Close Date & Time

01 SEP 2020 13:45

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

**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

01 SEP 2020 14:48

PC Open Date & Time

01 SEP 2020 14:40

PC Close Date & Time

02 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:04:14

**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

02 SEP 2020 16:54

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:04:14

**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

03 SEP 2020 12:46

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:04:14

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:04:14

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:04:14

**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

06 SEP 2020 15:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:04:14

**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

07 SEP 2020 12:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

**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 ☐

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 11:30
PC Open Date & Time	01 SEP 2020 11:15
PC Close Date & Time	01 SEP 2020 13:45

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

**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 ☐

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 14:48
PC Open Date & Time	01 SEP 2020 14:40
PC Close Date & Time	02 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:04:14

**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 ☒

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:04:14

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 16:56
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:04:14

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 ☒

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:46
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59



US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:04:14

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 ☐

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:04:14

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 ☐

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:04:14

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:04:14

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 ☒

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 15:25
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:04:14

**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 ☒

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:04:14

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:02
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3682040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:05:14

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT2

US3682040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:05:14

Generated On: 11 Aug 2021 23:04:14

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)	29 SEP 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:40
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG



US3682040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:05:14

Generated On: 11 Aug 2021 23:04:14

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

US3682040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:05:14

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3682040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

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 PARTICIPANT WITH VARICELLA ZOSTER ERUPTION IN TRIGEMINAL NERVE DISTRIBUTION. DUE TO CONCERN FOR REACTIVATION FOLLOWING IMMUNIZATION, STUDY PRODUCT WITHHELD.

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3682040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

09:44 (24 HR)

Collection date and time (derived)

29 SEP 2020 09:44

US3682040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:48	29 SEP 2020 09:48
Nasopharyngeal Swab 2	No		

US3682040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:05:13

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:12:03

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3682040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:03:45

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:03:45

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:03:45

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:03:45

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:05:14

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	VISIT3

US3682040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:05:14

Generated On: 11 Aug 2021 23:04:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	13:11 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 13:11
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:05:14

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3682040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:05:14

Generated On: 11 Aug 2021 23:04:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

13:35 (24 HR)

Collection date and time (derived)

27 OCT 2020 13:35



US3682040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:05:14

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

<b>TIMEPOINT</b>	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 <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	01 NOV 2020 19:46:28
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3682040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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

09 NOV 2020 17:03:12

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3682040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 07:22:53

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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	22 NOV 2020 16:14:43
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 06:19:28

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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	06 DEC 2020 12:20:17
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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

13 DEC 2020 14:28:51

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59



US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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	17 DEC 2020 00:11:42
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 00:01:53
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 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 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	31 DEC 2020 18:49:07
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 JAN 2021 08:09:17
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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

14 JAN 2021 00:01:59

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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

21 JAN 2021 19:18:28

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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

01 FEB 2021 12:56:08

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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

05 FEB 2021 06:40:24

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59



US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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

11 FEB 2021 22:55:00

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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

18 FEB 2021 00:01:35

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 21:15:53

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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	08 MAR 2021 08:29:49
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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 MAR 2021 17:11:41
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 14:30:49

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 18:24:22

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 05:21:57

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 14:45:58

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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

22 APR 2021 05:58:37

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 23:03:26

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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°F/38°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"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 278

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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°F/38°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"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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17 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUN 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 390

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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27 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 572

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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°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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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 ☐



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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°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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

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20 JUN 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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°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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

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04 JUL 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 691

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**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°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 ☐

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

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01 AUG 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

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08 AUG 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

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15 AUG 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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29 AUG 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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01 SEP 2022 00:01

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05 SEP 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

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12 SEP 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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15 SEP 2022 00:01

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19 SEP 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 SEP 2022 00:01

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26 SEP 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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"/>



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

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03 OCT 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

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

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

Date and time of submission

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10 OCT 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 OCT 2022 00:01

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17 OCT 2022 23:59

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US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 OCT 2022 00:01

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24 OCT 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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 <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**

**Generated On: 11 Aug 2021 23:04:14**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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31 OCT 2022 23:59

US3682040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

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**Folder: New Safety Follow Up Diary (1)**

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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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03 NOV 2022 00:01

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07 NOV 2022 23:59

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**US3682040**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 23:04:14**

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		08 MAR 2021 08:30:03

US3682040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:10:28

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:10:28

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3682040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

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*

US3682040

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 MAR 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

US3682040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	13:58 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 13:58
Temperature ( <i>xxx.x</i> )	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	77 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	176 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	108 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682040

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 MAR 2021

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

US3682040

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

14:22 (24 HR)

Collection date and time (derived)

29 MAR 2021 14:22



US3682040

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:43:28

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:33:40

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3682040**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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*

**US3682040**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 08 Apr 2021 17:59:29

Generated On: 11 Aug 2021 23:04:14

Date of Contact	24 DEC 2020
Time of Contact	12:12
Date and Time of Contact (derived)	24 DEC 2020 12:12
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Date of Visit	28 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	28 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

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Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

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Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Date of Contact	24 NOV 2020
Time of Contact	16:04
Date and Time of Contact (derived)	24 NOV 2020 16:04
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	100.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		360 of 2635
EAB) (1725)		

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		364 of 2635
EAB) (1725)		

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Date of Visit	25 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	25 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0



**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 01 Apr 2021 20:42:51

**Generated On: 11 Aug 2021 23:04:14**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	27 NOV 2020
Day 5	Yes	29 NOV 2020
Day 7	Yes	01 DEC 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 01 Apr 2021 20:42:51

**Generated On: 11 Aug 2021 23:04:14**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 DEC 2020
Day 5	Yes	01 JAN 2021
Day 7	Yes	03 JAN 2021
Day 9	Yes	05 JAN 2021
Day 14	Yes	10 JAN 2021
Day 21	Yes	17 JAN 2021
Day 28	Yes	25 JAN 2021

US3682040

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	SICKD1

US3682040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 NOV 2020
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 13:32
Height (xxx.x)	67 in
Weight (xxx.x)	84 kg
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TOUCHLESS
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682040

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 NOV 2020

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

US3682040

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 NOV 2020

US3682040

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3682040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	09:54 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 09:54
Height (xxx.x)	67 in
Weight (xxx.x)	196.8 lb
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	185 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	118 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3682040

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 DEC 2020

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

US3682040

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 DEC 2020

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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 \_\_\_\_\_

US3682040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

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)	
Height ( <i>xxx.x</i> )	
Weight ( <i>xxx.x</i> )	
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)	

US3682040

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:04:14

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.*

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 23:04:14**

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection \_\_\_\_\_

US3682040

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3682040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 JAN 2021
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 09:16
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3682040

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 JAN 2021

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

US3682040

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 JAN 2021

US3682040

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

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

Visit date (dd MMM yyyy)	4 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	UNBLND_DECIDE
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US3682040

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Date of updated informed consent ( <i>dd MMM yyyy</i> )	4 FEB 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 ( <i>dd MMM yyyy</i> )	4 FEB 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 type="radio"/> Not Administered <input checked="" 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

US3682040

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

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

US3682040

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

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)	4 FEB 2021
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 13:05
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3682040

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

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)	4 FEB 2021
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 14:25
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3682040

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 FEB 2021

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



US3682040

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

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) 4 FEB 2021

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 13:50

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

US3682040

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	04 FEB 2021
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Collection time (00:00-23:59)	13:35 (24 HR)
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Collection date and time (derived)	04 FEB 2021 13:35
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US3682040

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 FEB 2021
Collection time (00:00 - 23:59)	13:37
Collection Date and Time (derived)	04 FEB 2021 13:37

US3682040

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:10:28

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:10:28

Generated On: 11 Aug 2021 23:04:14

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

US3682040

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:29:10

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 MAR 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

US3682040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 18:29:11

Generated On: 11 Aug 2021 23:04:14

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)	1 MAR 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 14:15
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG



US3682040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 18:29:11

Generated On: 11 Aug 2021 23:04:14

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)	1 MAR 2021
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 15:07
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3682040

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:29:10

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 MAR 2021

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

US3682040

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 18:29:10

Generated On: 11 Aug 2021 23:04:14

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) 01 MAR 2021

What was the treatment time? (00:00-23:59) 14:32 (24 HR)

Treatment Date and Time (derived) 01 MAR 2021 14:32

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

US3682040

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:29:10

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:29:11

Generated On: 11 Aug 2021 23:04:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682040

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:29:11

Generated On: 11 Aug 2021 23:04:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682040

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3682040

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 MAR 2021
Time of assessment (00:00-23:59)	13:58 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 13:58
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	176 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	108 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3682040

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 MAR 2021

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

US3682040

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

14:22 (24 HR)

Collection date and time (derived)

29 MAR 2021 14:22

US3682040

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 21:11:49

Generated On: 11 Aug 2021 23:04:14

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3682040

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

AEID

Adverse event

HEADACHE

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)

15 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

419 of 2635

EAB) (1725)

US3682040

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

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	False
Concomitant Medication	True
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)	_____

US3682040

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

AEID

Adverse event

EXACERBATION OF  
VARICELLA ZOSTER

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)

01 SEP 2020

Start time (00:00-23:59)

23:00 (24 HR)

AE start date and time (derived)

01 SEP 2020 23:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

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 type="radio"/> Related <input checked="" 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 checked="" 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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

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PARTICIPANT REPORTS ONSET  
OF VESICULAR RASH  
CONSISTENT WITH VARICELLA  
ZOSTER IN V1 DISTRIBUTION  
OF TRIGEMINAL NERVE.  
PARTICIPANT BELIEVES  
SYMPTOMS STARTED PRIOR  
TO FIRST INJECTION, BUT NOT  
NOTED ON HISTORY OR  
PHYSICAL EXAM AT THAT  
TIME. NO EYE PAIN, NO VISUAL  
CHANGES. ON PHYSICAL  
EXAM, ALL LESIONS  
CRUSTING WITH NO VISIBLE  
VESICLES. REFERRED TO PMD  
FOR EVALUATION AND  
ACYCLOVIR TREATMENT. DUE  
TO CONCERN FOR POSSIBLE  
REACTIVATION FROM IMMUNE  
ACTIVATION WITH SECOND  
INJECTION, STUDY PRODUCT  
DISCONTINUED.

---

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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US3682040

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

AEID	USA-US081-2021-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID 19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	21 DEC 2020
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)	1 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

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	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 (4)

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

AEID	
Adverse event	COVID-LIKE ILLNESS
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)	22 NOV 2020
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)	26 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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

Form: Adverse Events (4)

Data signed: (b) (4) 01 Apr 2021 20:42:49

Generated On: 11 Aug 2021 23:04:14

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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
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)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 20:42:50

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

Yes ☒

No ☐

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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) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Name of Medication NIFEDIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 30

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) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 1000

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 (2)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication LOWER BACK PAIN

Dose per administration 300

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) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

	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)	1 SEP 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) _____		
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 (4)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Name of Medication ROBOXIN

Prophylaxis Yes ☐  
No ☒

Indication LOWER BACK PAIN

Dose per administration 750

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) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

	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)	1 SEP 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) _____		
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 (5)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication COVID-LIKE ILLNESS (BODY  
ACHES, HEADACHE)

Dose per administration 1000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID19;  
HEADACHE

Dose per administration 1000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

	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)	28 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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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US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 APR 2021
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"/>

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

Name of Medication NIFEDIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 30

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)

445 of 2635

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 16:44:22

Generated On: 11 Aug 2021 23:04:14

	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)	19 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"/>

US3682040

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 20:42:50

Generated On: 11 Aug 2021 23:04:14

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---



US3682040

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 01 Apr 2021 20:42:51

Generated On: 11 Aug 2021 23:04:14

---

Date of dosing discontinuation (dd MMM yyyy) 29 SEP 2020

---

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #2

---

US3682040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:04:14

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 ☐

US3682040

Folder: SAE USA-US081-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

SAEID	USA-US081-2021-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3682040

Folder: SAE USA-US081-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

SAEID	USA-US081-2021-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	07/JAN/2021 15:51
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

US3682040

Folder: SAE USA-US081-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 20:42:52

Generated On: 11 Aug 2021 23:04:14

SAEID	USA-US081-2021-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/JAN/2021 19:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3682040 (Prod: UCLA Vine Street Clinic - (CRS))

**US3682040**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 23:04:14**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'US3682040'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 16:30:10

**US3682040**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:05:03
	(b) (4)	



**US3682040**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 16:34:22

**US3682040**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Clinic (Clinic)'	Jesse Clark (b) (4)	01 Sep 2020 17:05:03

**US3682040**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered 'SCRN'	System	01 Sep 2020 17:05:03

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered (b) (6) 1971'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 16:34:23

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '48'	Jesse Clark (b) (4)	01 Sep 2020 17:05:24

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered 'YEARS'	System	01 Sep 2020 17:05:24

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered '49'	System	01 Sep 2020 17:05:42

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Male (M)'	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:05:24
	(b) (4)	



**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jesse Clark (b) (4)	01 Sep 2020 17:05:24

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:05:24

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:05:24

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:05:24

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:05:24

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:05:24

US3682040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:04:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User closed query 'Per CDM: Other has been selected for Race, however, please review the predefined options and update if appropriate' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:43:22
User signature succeeded.	Jesse Clark (b) (4)	20 Apr 2021 18:41:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:27:20
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Apr 2021 17:27:20
Query 'Per CDM: Other has been selected for Race, however, please review the predefined options and update if appropriate' answered with 'options reviewed with participant. Participant still stands by " I don't know how to answer" ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 17:04:33
User opened query 'Per CDM: Other has been selected for Race, however, please review the predefined options and update if appropriate' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 01:08:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '1'	(b) (4) Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:05:24

US3682040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:04:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	20 Apr 2021 18:41:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:27:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 17:27:20
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'I don't know how to answer'	(b) (4) Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:05:24



**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	20 Apr 2021 18:41:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:27:20
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Apr 2021 17:27:20
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	(b) (4) Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:05:24

**US3682040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:04:14**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:05:24
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '1 Sep 2020'	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:05:42
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered 'Sep 2020'	System	01 Sep 2020 17:05:42

**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered '2020'	System	01 Sep 2020 17:05:42

**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Amendment 3 (3)'	Jesse Clark (b) (4)	01 Sep 2020 17:05:42

**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4)	01 Sep 2020 17:05:42
	Jesse Clark (b) (4)	
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:05:42



**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:05:42
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:05:42
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 16:34:22

**US3682040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:04:14**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered 'I'	System	01 Sep 2020 17:05:47

**US3682040**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:05:47
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 23:04:14**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4)	01 Sep 2020 17:05:52
	Jesse Clark (b) (4)	
	(b) (4)	

US3682040

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:04:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:07:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:07:49
Data point term sent to Coder	System	01 Sep 2020 17:07:00
User entered 'Hypertension'	Jesse Clark (b) (4)	01 Sep 2020 17:06:08

**US3682040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'un UNK 2016'	Jesse Clark (b) (4)	01 Sep 2020 17:06:08



**US3682040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:06:08

**US3682040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4)	01 Sep 2020 17:06:08
	Jesse Clark (b) (4)	
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	Jesse Clark (b) (4)	01 Sep 2020 17:06:08

**US3682040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:06:08

**US3682040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered 'Jan 2016'	System	01 Sep 2020 17:06:08

**US3682040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered '2016'	System	01 Sep 2020 17:06:08

**US3682040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered empty.	System	01 Sep 2020 17:06:08

**US3682040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered empty.	System	01 Sep 2020 17:06:08



US3682040

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:04:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Lumbar disc herniation - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 04:30:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 04:30:48
Data point term sent to Coder	System	23 Sep 2020 17:49:21
User entered 'LBP, DISC HERNIATION, L4 & L5' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 17:48:25
Data point term sent to Coder	System	23 Sep 2020 17:48:20
User entered 'DISC HERNIATION, L4 & L5, LBP' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 17:47:57
Data point term sent to Coder	System	23 Sep 2020 17:47:19
User entered 'Disc Herniation, L4 & L5'	(b) (4), (b) (6)	23 Sep 2020 17:47:06

**US3682040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '1 Sep 2015'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:06

**US3682040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:06

**US3682040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:06

**US3682040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:06

**US3682040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:06

**US3682040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered 'Sep 2015'	System	23 Sep 2020 17:47:06

**US3682040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered '2015'	System	23 Sep 2020 17:47:06



**US3682040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered empty.	System	23 Sep 2020 17:47:06

**US3682040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered empty.	System	23 Sep 2020 17:47:06

US3682040

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:04:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Varicella zoster virus infection, LLT: Varicella zoster - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:29:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:29:57
Data point term sent to Coder	System	16 Oct 2020 20:07:51
User entered 'Varicella zoster'	Susan Reed (b) (4)	16 Oct 2020 20:07:44

**US3682040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'un Aug 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:07:44

**US3682040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:07:44

**US3682040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:07:44

**US3682040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:07:44

**US3682040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:07:44



**US3682040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered 'Aug 2020'	System	16 Oct 2020 20:07:44

**US3682040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered '2020'	System	16 Oct 2020 20:07:44

**US3682040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered empty.	System	16 Oct 2020 20:07:44

**US3682040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User entered empty.	System	16 Oct 2020 20:07:44

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:44:25
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '1 Sep 2020'	(b) (4) Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:44:25

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '09:35'	Jesse Clark (b) (4)	01 Sep 2020 17:44:25

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User entered '1 Sep 2020 09:35'	System	01 Sep 2020 17:44:25



**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '168' cm	(b) (4) Jesse Clark (b) (4)	01 Sep 2020 17:44:25
DataPoint set to visible.	(b) (4) System	01 Sep 2020 17:05:47

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '84' kg	(b) (4) Jesse Clark (b) (4)	01 Sep 2020 17:44:25
DataPoint set to visible.	(b) (4) System	01 Sep 2020 17:05:47

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User entered '29.76190'	System	01 Sep 2020 17:44:25
DataPoint set to visible.	System	01 Sep 2020 17:05:47

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User entered 'kg/m2'	System	01 Sep 2020 17:44:25
DataPoint set to visible.	System	01 Sep 2020 17:05:47

US3682040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User closed query 'Re-Query :Per CDM: Response noted, kindly consider updating the unit as Blank as Temperature is ND. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 05:36:14
Query 'Re-Query :Per CDM: Response noted, kindly consider updating the unit as Blank as Temperature is ND. ' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 17:13:36
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 17:13:11
User opened query 'Re-Query :Per CDM: Response noted, kindly consider updating the unit as Blank as Temperature is ND. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:28:29
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:28:29
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Screening and visit 1 done same day' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:23:16
User entered missing code ND - Not Done; reason for change Per Query Resolution	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:23:10

US3682040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:41:53
User entered '97.5' F	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:44:25

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Susan Reed (b) (4)	09 Sep 2020 17:23:10
User entered 'Oral (Oral)'	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:44:25
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	Jesse Clark (b) (4)	01 Sep 2020 17:44:25



US3682040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	09 Sep 2020 17:23:10
User entered '81'	Susan Reed (b) (4)	01 Sep 2020 17:44:25
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User entered 'bpm'	System	01 Sep 2020 17:44:25

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	09 Sep 2020 17:23:10
User entered '16'	Susan Reed (b) (4)	01 Sep 2020 17:44:25
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User entered 'breaths/min'	System	01 Sep 2020 17:44:25

US3682040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	09 Sep 2020 17:23:10
User entered '127'	Susan Reed (b) (4)	01 Sep 2020 17:44:25
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User entered 'mmHg'	System	01 Sep 2020 17:44:25

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	09 Sep 2020 17:23:10
User entered '87'	Susan Reed (b) (4)	01 Sep 2020 17:44:25
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37
User entered 'mmHg'	System	01 Sep 2020 17:44:25



**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37

**US3682040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:37

**US3682040**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	01 Sep 2020 17:06:51
	(b) (4)	

**US3682040**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '1 Sep 2020'	Jesse Clark (b) (4)	01 Sep 2020 17:06:51

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38



US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	(b) (4) Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

**US3682040**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:04:14**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'No (N)'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38



**US3682040**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

**US3682040**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:04:14**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'I'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

US3682040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38

**US3682040**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:04:14**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '0'	Jesse Clark (b) (4)	01 Sep 2020 17:06:38



**US3682040**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:29
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:06:38

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:49

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:49

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:49

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'VISIT1'	System	01 Sep 2020 19:08:49

US3682040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 17:05:27

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '110472'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 17:05:27

US3682040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 17:05:27



US3682040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:04:14

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)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 12:09:49
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Form completed' (Site from DM).	Susan Reed (b) (4) (b) (4)	04 Sep 2020 00:43:56
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	04 Sep 2020 00:43:47
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 19:01:53

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:04:14**

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)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'No (N)'	Susan Reed (b) (4)	04 Sep 2020 00:43:47

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	04 Sep 2020 00:43:47

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:04:14**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	04 Sep 2020 00:43:47

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:04:14**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	04 Sep 2020 00:43:47

US3682040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:04:14

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 11:34:49
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'data added' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	08 Dec 2020 16:38:03
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	08 Dec 2020 16:37:57
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 23:41:31
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:57:10
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:57:09

US3682040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:04:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User closed query 'Per CDM: Re-query: ND (Not done) noted for HEIGHT and WEIGHT, however, please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:48:05
Query 'Per CDM: Re-query: ND (Not done) noted for HEIGHT and WEIGHT, however, please also keep the Units blank for both the data-fields. Thank you.'	(b) (4), (b) (6)	10 Sep 2020 17:13:55
answered with 'update complete' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 17:13:50
User opened query 'Per CDM: Re-query: ND (Not done) noted for HEIGHT and WEIGHT, however, please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:35:29
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:35:29
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and Day 1 completed on same day' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 19:58:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:58:02
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:42:13
User entered '168' cm	(b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 17:13:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:58:02
User entered '84' kg	(b) (4), (b) (6)	01 Sep 2020 19:13:45



US3682040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:04:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User closed query 'Per CDM: Re-query: ND (Not done) noted for HEIGHT and WEIGHT, however, please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:48:05
Query 'Per CDM: Re-query: ND (Not done) noted for HEIGHT and WEIGHT, however, please also keep the Units blank for both the data-fields. Thank you.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 17:13:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 17:13:50
User opened query 'Per CDM: Re-query: ND (Not done) noted for HEIGHT and WEIGHT, however, please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:35:29
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:35:29
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and Day 1 completed on same day' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 19:58:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:58:02
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:42:13
User entered '168' cm	(b) (4), (b) (6)	01 Sep 2020 19:13:45

US3682040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:04:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:13:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:58:02
User entered '84' kg	(b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '09:35'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '01 Sep 2020 09:35'	System	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45



**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '81'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'bpm'	System	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'breaths/min'	System	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '127'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'mmHg'	System	01 Sep 2020 19:13:45



**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '87'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'mmHg'	System	01 Sep 2020 19:13:45

US3682040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:04:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User closed query 'Per CDM: Re-query: ND (Not done) noted for HEIGHT and WEIGHT, however, please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:48:05
Query 'Per CDM: Re-query: ND (Not done) noted for HEIGHT and WEIGHT, however, please also keep the Units blank for both the data-fields. Thank you.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 17:13:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 17:13:50
User opened query 'Per CDM: Re-query: ND (Not done) noted for HEIGHT and WEIGHT, however, please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:35:29
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:35:29
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and Day 1 completed on same day' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 19:58:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:58:02
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:42:13
User entered '168' cm	(b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 17:13:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:58:02
User entered '84' kg	(b) (4), (b) (6)	01 Sep 2020 19:13:45

US3682040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:04:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '11:28'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45



**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '1 Sep 2020 11:28'	System	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '75'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'bpm'	System	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'breaths/min'	System	01 Sep 2020 19:13:45



**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '130'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'mmHg'	System	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '88'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'mmHg'	System	01 Sep 2020 19:13:45

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:17:13

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:17:13

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:09

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:09



US3682040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:04:14

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)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:09

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:09

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '10:55'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:09

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '1 Sep 2020 10:55'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:59:09

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'ONCE'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 17:59:09



**US3682040**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:26:11

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:26:11

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '10:21'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:26:11

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '01 Sep 2020 10:21'	System	02 Sep 2020 18:26:11

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 23:04:14**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:25:59

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 18:25:59

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:25:59

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered '10:18'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:25:59



**US3682040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '01 Sep 2020 10:18'	System	02 Sep 2020 18:25:59

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Sep 2020 18:25:59

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:25:59

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:25:59

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	02 Sep 2020 18:25:59

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Sep 2020 22:53:19

**US3682040**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'I'	System	08 Sep 2020 22:53:19

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:59:09



US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:29:06', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'c24b0591-a8a2-4b45-8404-9fd7c6573836'	System	01 Sep 2020 18:29:42
User entered 'Yes (Y)'	System	01 Sep 2020 18:29:42

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:29:12', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'c24b0591-a8a2-4b45-8404-9fd7c6573836'	System	01 Sep 2020 18:29:42
User entered '97.9'	System	01 Sep 2020 18:29:42

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:29:27', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'c24b0591-a8a2-4b45-8404-9fd7c6573836'	System	01 Sep 2020 18:29:42
User entered 'No (N)'	System	01 Sep 2020 18:29:42

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:29:38', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'c24b0591-a8a2-4b45-8404-9fd7c6573836'	System	01 Sep 2020 18:29:42
User entered '01 Sep 2020 11:29'	System	01 Sep 2020 18:29:42

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '01 Sep 2020 11:15'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '01 Sep 2020 13:45'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:46:59', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '71a7e48b-0cec-45f3-890d-6684d8dddb4e'	System	01 Sep 2020 21:47:22
User entered 'Yes (Y)'	System	01 Sep 2020 21:47:22



US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:47:04', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '71a7e48b-0cec-45f3-890d-6684d8dddb4e'	System	01 Sep 2020 21:47:22
User entered '97.7'	System	01 Sep 2020 21:47:22

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:47:10', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '71a7e48b-0cec-45f3-890d-6684d8dddb4e'	System	01 Sep 2020 21:47:22
User entered 'No (N)'	System	01 Sep 2020 21:47:22

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:47:18', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '71a7e48b-0cec-45f3-890d-6684d8dddb4e'	System	01 Sep 2020 21:47:22
User entered '01 Sep 2020 14:47'	System	01 Sep 2020 21:47:22

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '01 Sep 2020 14:40'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 2'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:04:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:02', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'abb14153-6d22-428b-98be-444b10059cc5'	System	02 Sep 2020 23:54:22
User entered 'Yes (Y)'	System	02 Sep 2020 23:54:22

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:04:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:08', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'abb14153-6d22-428b-98be-444b10059cc5'	System	02 Sep 2020 23:54:22
User entered '98.3'	System	02 Sep 2020 23:54:22



US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:13', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'abb14153-6d22-428b-98be-444b10059cc5'	System	02 Sep 2020 23:54:22
User entered 'No (N)'	System	02 Sep 2020 23:54:22

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:20', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'abb14153-6d22-428b-98be-444b10059cc5'	System	02 Sep 2020 23:54:22
User entered '02 Sep 2020 16:54'	System	02 Sep 2020 23:54:22

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 3'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:04:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:45:19', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '53469b44-fbe9-4148-b9e1-6e0d66b94c8d'	System	03 Sep 2020 19:45:39
User entered 'Yes (Y)'	System	03 Sep 2020 19:45:39

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:04:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:45:24', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '53469b44-fbe9-4148-b9e1-6e0d66b94c8d' User entered '97.7'	System	03 Sep 2020 19:45:39
	System	03 Sep 2020 19:45:39

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:45:30', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '53469b44-fbe9-4148-b9e1-6e0d66b94c8d'	System	03 Sep 2020 19:45:39
User entered 'No (N)'	System	03 Sep 2020 19:45:39



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:45:35', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '53469b44-fbe9-4148-b9e1-6e0d66b94c8d'	System	03 Sep 2020 19:45:39
User entered '03 Sep 2020 12:45'	System	03 Sep 2020 19:45:39

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 4'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:04:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:04:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:04:14

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44



US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:04:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 5'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:04:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:04:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44



US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:04:14

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:04:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 6'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:04:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:23:57', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'a96cbdd7-0ed6-4eb4-91cf-d907441c17a5'	System	06 Sep 2020 22:24:18
User entered 'Yes (Y)'	System	06 Sep 2020 22:24:18

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:04:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:04', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'a96cbdd7-0ed6-4eb4-91cf-d907441c17a5'	System	06 Sep 2020 22:24:18
User entered '97.3'	System	06 Sep 2020 22:24:18



US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:10', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'a96cbdd7-0ed6-4eb4-91cf-d907441c17a5'	System	06 Sep 2020 22:24:18
User entered 'No (N)'	System	06 Sep 2020 22:24:18

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:14', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'a96cbdd7-0ed6-4eb4-91cf-d907441c17a5'	System	06 Sep 2020 22:24:18
User entered '06 Sep 2020 15:24'	System	06 Sep 2020 22:24:18

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 7'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:04:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:00:30', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '3293acd8-3fdf-4878-95f4-189b4678006b'	System	07 Sep 2020 19:01:08
User entered 'Yes (Y)'	System	07 Sep 2020 19:01:08

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:04:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:00:43', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '3293acd8-3fdf-4878-95f4-189b4678006b' User entered '97.1'	System	07 Sep 2020 19:01:08
	System	07 Sep 2020 19:01:08

US3682040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:00:51', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '3293acd8-3fdf-4878-95f4-189b4678006b'	System	07 Sep 2020 19:01:08
User entered 'No (N)'	System	07 Sep 2020 19:01:08



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:00:58', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '3293acd8-3fdf-4878-95f4-189b4678006b'	System	07 Sep 2020 19:01:08
User entered '07 Sep 2020 12:00'	System	07 Sep 2020 19:01:08

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:29:54', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '1ebeb917-0dbf-4afc-9000-1abd8d7ae8c9'	System	01 Sep 2020 18:30:22
User entered 'None (1)'	System	01 Sep 2020 18:30:22

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:02', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '1ebeb917-0dbf-4afc-9000-1abd8d7ae8c9'	System	01 Sep 2020 18:30:22
User entered 'No (N)'	System	01 Sep 2020 18:30:22

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:07', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '1ebeb917-0dbf-4afc-9000-1abd8d7ae8c9'	System	01 Sep 2020 18:30:22
User entered 'No (N)'	System	01 Sep 2020 18:30:22

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:14', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '1ebeb917-0dbf-4afc-9000-1abd8d7ae8c9'	System	01 Sep 2020 18:30:22
User entered 'None (1)'	System	01 Sep 2020 18:30:22



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:18', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '1ebeb917-0dbf-4afc-9000-1abd8d7ae8c9'	System	01 Sep 2020 18:30:22
User entered '01 Sep 2020 11:30'	System	01 Sep 2020 18:30:22

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '01 Sep 2020 11:15'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '01 Sep 2020 13:45'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:47:30', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '97ceeb21-ddb3-44ca-b34e-96a2a61733d0'	System	01 Sep 2020 21:48:09
User entered 'None (1)'	System	01 Sep 2020 21:48:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:47:37', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '97ceeb21-ddb3-44ca-b34e-96a2a61733d0'	System	01 Sep 2020 21:48:09
User entered 'No (N)'	System	01 Sep 2020 21:48:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:47:44', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '97ceeb21-ddb3-44ca-b34e-96a2a61733d0'	System	01 Sep 2020 21:48:09
User entered 'No (N)'	System	01 Sep 2020 21:48:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:47:55', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '97ceeb21-ddb3-44ca-b34e-96a2a61733d0'	System	01 Sep 2020 21:48:09
User entered 'None (1)'	System	01 Sep 2020 21:48:09



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:48:03', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '97ceeb21-ddb3-44ca-b34e-96a2a61733d0'	System	01 Sep 2020 21:48:09
User entered '01 Sep 2020 14:48'	System	01 Sep 2020 21:48:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '01 Sep 2020 14:40'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 2'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:28', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '663d4291-e40f-4dc6-a275-3e56a18184bc'	System	02 Sep 2020 23:54:54
User entered 'None (1)'	System	02 Sep 2020 23:54:54

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:04:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:32', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '663d4291-e40f-4dc6-a275-3e56a18184bc'	System	02 Sep 2020 23:54:54
User entered 'No (N)'	System	02 Sep 2020 23:54:54

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:38', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '663d4291-e40f-4dc6-a275-3e56a18184bc'	System	02 Sep 2020 23:54:54
User entered 'No (N)'	System	02 Sep 2020 23:54:54

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:44', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '663d4291-e40f-4dc6-a275-3e56a18184bc'	System	02 Sep 2020 23:54:54
User entered 'None (1)'	System	02 Sep 2020 23:54:54



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:49', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '663d4291-e40f-4dc6-a275-3e56a18184bc'	System	02 Sep 2020 23:54:54
User entered '02 Sep 2020 16:54'	System	02 Sep 2020 23:54:54

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 3'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:45:44', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '237e4eaa-07eb-49bc-b474-e7626d13abdb'	System	03 Sep 2020 19:46:09
User entered 'None (1)'	System	03 Sep 2020 19:46:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:04:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:45:51', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '237e4eaa-07eb-49bc-b474-e7626d13abdb'	System	03 Sep 2020 19:46:09
User entered 'No (N)'	System	03 Sep 2020 19:46:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:45:54', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '237e4eaa-07eb-49bc-b474-e7626d13abdb'	System	03 Sep 2020 19:46:09
User entered 'No (N)'	System	03 Sep 2020 19:46:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:45:58', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '237e4eaa-07eb-49bc-b474-e7626d13abdb'	System	03 Sep 2020 19:46:09
User entered 'None (1)'	System	03 Sep 2020 19:46:09



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:46:04', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '237e4eaa-07eb-49bc-b474-e7626d13abdb'	System	03 Sep 2020 19:46:09
User entered '03 Sep 2020 12:46'	System	03 Sep 2020 19:46:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 4'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:04:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:04:14

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44



US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:04:14

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 5'	System	01 Sep 2020 17:59:09

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:04:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44



US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:04:14

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:04:14

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 6'	System	01 Sep 2020 17:59:09



US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:20', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '76fe0867-6742-43d8-b508-bee8844f33e8'	System	06 Sep 2020 22:24:43
User entered 'None (1)'	System	06 Sep 2020 22:24:43

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:04:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:25', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '76fe0867-6742-43d8-b508-bee8844f33e8'	System	06 Sep 2020 22:24:43
User entered 'No (N)'	System	06 Sep 2020 22:24:43

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:29', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '76fe0867-6742-43d8-b508-bee8844f33e8'	System	06 Sep 2020 22:24:43
User entered 'No (N)'	System	06 Sep 2020 22:24:43

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:35', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '76fe0867-6742-43d8-b508-bee8844f33e8'	System	06 Sep 2020 22:24:43
User entered 'None (1)'	System	06 Sep 2020 22:24:43

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:38', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '76fe0867-6742-43d8-b508-bee8844f33e8'	System	06 Sep 2020 22:24:43
User entered '06 Sep 2020 15:24'	System	06 Sep 2020 22:24:43

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 7'	System	01 Sep 2020 17:59:09



US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:12', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'f06dcf7b-2dd5-4555-9e77-58ed3d2eb58c'	System	07 Sep 2020 19:01:41
User entered 'None (1)'	System	07 Sep 2020 19:01:41

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:04:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:17', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'f06dcf7b-2dd5-4555-9e77-58ed3d2eb58c'	System	07 Sep 2020 19:01:41
User entered 'No (N)'	System	07 Sep 2020 19:01:41

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:22', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'f06dcf7b-2dd5-4555-9e77-58ed3d2eb58c'	System	07 Sep 2020 19:01:41
User entered 'No (N)'	System	07 Sep 2020 19:01:41

US3682040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:04:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:31', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'f06dcf7b-2dd5-4555-9e77-58ed3d2eb58c'	System	07 Sep 2020 19:01:41
User entered 'None (1)'	System	07 Sep 2020 19:01:41

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:34', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'f06dcf7b-2dd5-4555-9e77-58ed3d2eb58c'	System	07 Sep 2020 19:01:41
User entered '07 Sep 2020 12:01'	System	07 Sep 2020 19:01:41

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:59:09



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:28', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '315fa331-e385-48c8-80ac-70b2f2aafaf7'	System	01 Sep 2020 18:30:57
User entered 'None (0)'	System	01 Sep 2020 18:30:57

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:31', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '315fa331-e385-48c8-80ac-70b2f2aafaf7'	System	01 Sep 2020 18:30:57
User entered 'None (0)'	System	01 Sep 2020 18:30:57

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:35', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '315fa331-e385-48c8-80ac-70b2f2aafaf7'	System	01 Sep 2020 18:30:57
User entered 'None (0)'	System	01 Sep 2020 18:30:57

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:38', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '315fa331-e385-48c8-80ac-70b2f2aafaf7'	System	01 Sep 2020 18:30:57
User entered 'None (0)'	System	01 Sep 2020 18:30:57

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:41', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '315fa331-e385-48c8-80ac-70b2f2aafaf7'	System	01 Sep 2020 18:30:57
User entered 'None (0)'	System	01 Sep 2020 18:30:57

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:43', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '315fa331-e385-48c8-80ac-70b2f2aafaf7'	System	01 Sep 2020 18:30:57
User entered 'None (0)'	System	01 Sep 2020 18:30:57

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:04:14

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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:50', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '315fa331-e385-48c8-80ac-70b2f2aafaf7'	System	01 Sep 2020 18:30:57
User entered 'No (N)'	System	01 Sep 2020 18:30:57

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T11:30:52', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '315fa331-e385-48c8-80ac-70b2f2aafaf7'	System	01 Sep 2020 18:30:57
User entered '01 Sep 2020 11:30'	System	01 Sep 2020 18:30:57



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '01 Sep 2020 11:15'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '01 Sep 2020 13:45'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:48:21', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '2a3c985b-d968-40b2-a3b7-d14f16b296c1'	System	01 Sep 2020 21:48:58
User entered 'No interference with activity (1)'	System	01 Sep 2020 21:48:58

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:48:28', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '2a3c985b-d968-40b2-a3b7-d14f16b296c1'	System	01 Sep 2020 21:48:58
User entered 'None (0)'	System	01 Sep 2020 21:48:58

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:48:32', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '2a3c985b-d968-40b2-a3b7-d14f16b296c1'	System	01 Sep 2020 21:48:58
User entered 'None (0)'	System	01 Sep 2020 21:48:58

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:48:36', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '2a3c985b-d968-40b2-a3b7-d14f16b296c1'	System	01 Sep 2020 21:48:58
User entered 'None (0)'	System	01 Sep 2020 21:48:58

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:48:39', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '2a3c985b-d968-40b2-a3b7-d14f16b296c1'	System	01 Sep 2020 21:48:58
User entered 'None (0)'	System	01 Sep 2020 21:48:58



US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:48:42', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '2a3c985b-d968-40b2-a3b7-d14f16b296c1'	System	01 Sep 2020 21:48:58
User entered 'None (0)'	System	01 Sep 2020 21:48:58

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:04:14

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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:48:49', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '2a3c985b-d968-40b2-a3b7-d14f16b296c1'	System	01 Sep 2020 21:48:58
User entered 'No (N)'	System	01 Sep 2020 21:48:58

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-01T14:48:55', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '2a3c985b-d968-40b2-a3b7-d14f16b296c1'	System	01 Sep 2020 21:48:58
User entered '01 Sep 2020 14:48'	System	01 Sep 2020 21:48:58

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '01 Sep 2020 14:40'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 2'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:55', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e5b85669-258f-4fa9-9a58-351eb915186a'	System	02 Sep 2020 23:56:27
User entered 'None (0)'	System	02 Sep 2020 23:56:27

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:54:59', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e5b85669-258f-4fa9-9a58-351eb915186a'	System	02 Sep 2020 23:56:27
User entered 'None (0)'	System	02 Sep 2020 23:56:27



US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:04:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:55:03', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e5b85669-258f-4fa9-9a58-351eb915186a'	System	02 Sep 2020 23:56:27
User entered 'None (0)'	System	02 Sep 2020 23:56:27

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:55:06', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e5b85669-258f-4fa9-9a58-351eb915186a' User entered 'None (0)'	System	02 Sep 2020 23:56:27
	System	02 Sep 2020 23:56:27

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:55:09', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e5b85669-258f-4fa9-9a58-351eb915186a'	System	02 Sep 2020 23:56:27
User entered 'None (0)'	System	02 Sep 2020 23:56:27

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:56:15', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e5b85669-258f-4fa9-9a58-351eb915186a'	System	02 Sep 2020 23:56:27
User entered 'None (0)'	System	02 Sep 2020 23:56:27

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:04:14

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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:56:20', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e5b85669-258f-4fa9-9a58-351eb915186a'	System	02 Sep 2020 23:56:27
User entered 'No (N)'	System	02 Sep 2020 23:56:27

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-02T16:56:24', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e5b85669-258f-4fa9-9a58-351eb915186a'	System	02 Sep 2020 23:56:27
User entered '02 Sep 2020 16:56'	System	02 Sep 2020 23:56:27

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:59:09



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 3'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:46:09', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '05b8896c-dce4-4c31-bec8-3369422887de'	System	03 Sep 2020 19:46:49
User entered 'None (0)'	System	03 Sep 2020 19:46:49

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:46:14', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '05b8896c-dce4-4c31-bec8-3369422887de'	System	03 Sep 2020 19:46:49
User entered 'None (0)'	System	03 Sep 2020 19:46:49

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:04:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:46:18', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '05b8896c-dce4-4c31-bec8-3369422887de'	System	03 Sep 2020 19:46:49
User entered 'None (0)'	System	03 Sep 2020 19:46:49

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:04:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:46:23', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '05b8896c-dce4-4c31-bec8-3369422887de'	System	03 Sep 2020 19:46:49
User entered 'None (0)'	System	03 Sep 2020 19:46:49

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:46:28', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '05b8896c-dce4-4c31-bec8-3369422887de'	System	03 Sep 2020 19:46:49
User entered 'None (0)'	System	03 Sep 2020 19:46:49

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:46:30', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '05b8896c-dce4-4c31-bec8-3369422887de'	System	03 Sep 2020 19:46:49
User entered 'None (0)'	System	03 Sep 2020 19:46:49

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:04:14

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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:46:41', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '05b8896c-dce4-4c31-bec8-3369422887de'	System	03 Sep 2020 19:46:49
User entered 'No (N)'	System	03 Sep 2020 19:46:49



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-03T12:46:44', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '05b8896c-dce4-4c31-bec8-3369422887de'	System	03 Sep 2020 19:46:49
User entered '03 Sep 2020 12:46'	System	03 Sep 2020 19:46:49

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 4'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:04:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:04:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:04:14

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)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 5'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:04:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:04:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:04:14

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)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:59:09



**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 6'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:44', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '32e5fe93-d7b0-4db5-ba16-49bb7b430597'	System	06 Sep 2020 22:25:07
User entered 'None (0)'	System	06 Sep 2020 22:25:07

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:47', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '32e5fe93-d7b0-4db5-ba16-49bb7b430597'	System	06 Sep 2020 22:25:07
User entered 'None (0)'	System	06 Sep 2020 22:25:07

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:04:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:49', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '32e5fe93-d7b0-4db5-ba16-49bb7b430597'	System	06 Sep 2020 22:25:07
User entered 'None (0)'	System	06 Sep 2020 22:25:07

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:52', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '32e5fe93-d7b0-4db5-ba16-49bb7b430597'	System	06 Sep 2020 22:25:07
User entered 'None (0)'	System	06 Sep 2020 22:25:07

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:54', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '32e5fe93-d7b0-4db5-ba16-49bb7b430597'	System	06 Sep 2020 22:25:07
User entered 'None (0)'	System	06 Sep 2020 22:25:07

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:24:56', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '32e5fe93-d7b0-4db5-ba16-49bb7b430597'	System	06 Sep 2020 22:25:07
User entered 'None (0)'	System	06 Sep 2020 22:25:07



US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:04:14

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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:25:01', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '32e5fe93-d7b0-4db5-ba16-49bb7b430597'	System	06 Sep 2020 22:25:07
User entered 'No (N)'	System	06 Sep 2020 22:25:07

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-06T15:25:04', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '32e5fe93-d7b0-4db5-ba16-49bb7b430597'	System	06 Sep 2020 22:25:07
User entered '06 Sep 2020 15:25'	System	06 Sep 2020 22:25:07

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 7'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:40', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '51a9a5eb-2129-4bd2-8f4d-8fd2e5430b62'	System	07 Sep 2020 19:02:16
User entered 'None (0)'	System	07 Sep 2020 19:02:16

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:43', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '51a9a5eb-2129-4bd2-8f4d-8fd2e5430b62'	System	07 Sep 2020 19:02:16
User entered 'None (0)'	System	07 Sep 2020 19:02:16

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:47', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '51a9a5eb-2129-4bd2-8f4d-8fd2e5430b62'	System	07 Sep 2020 19:02:16
User entered 'None (0)'	System	07 Sep 2020 19:02:16



US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:04:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:52', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '51a9a5eb-2129-4bd2-8f4d-8fd2e5430b62'	System	07 Sep 2020 19:02:16
User entered 'None (0)'	System	07 Sep 2020 19:02:16

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:55', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '51a9a5eb-2129-4bd2-8f4d-8fd2e5430b62'	System	07 Sep 2020 19:02:16
User entered 'None (0)'	System	07 Sep 2020 19:02:16

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:01:58', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '51a9a5eb-2129-4bd2-8f4d-8fd2e5430b62'	System	07 Sep 2020 19:02:16
User entered 'None (0)'	System	07 Sep 2020 19:02:16

US3682040

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:04:14

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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:02:06', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '51a9a5eb-2129-4bd2-8f4d-8fd2e5430b62'	System	07 Sep 2020 19:02:16
User entered 'No (N)'	System	07 Sep 2020 19:02:16

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-09-07T12:02:09', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '51a9a5eb-2129-4bd2-8f4d-8fd2e5430b62'	System	07 Sep 2020 19:02:16
User entered '07 Sep 2020 12:02'	System	07 Sep 2020 19:02:16

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:04:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Sep 2020 23:01:47



**US3682040**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '8 Sep 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Sep 2020 23:01:47

**US3682040**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Sep 2020 23:01:47

**US3682040**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4) Susan Reed (b) (4)	08 Sep 2020 23:01:47

**US3682040**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Sep 2020 22:46:13

**US3682040**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'I'	System	15 Sep 2020 22:46:13

**US3682040**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:31:39

**US3682040**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '15 Sep 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:31:39

**US3682040**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:31:39



**US3682040**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:31:39

**US3682040**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:31:45

**US3682040**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'I'	System	15 Sep 2020 23:31:45

**US3682040**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	Jesse Clark (b) (4)	29 Sep 2020 16:49:35

**US3682040**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '22 Sep 2020'	Jesse Clark (b) (4)	29 Sep 2020 16:49:35

**US3682040**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Contact Made (CONTACT MADE)'	Jesse Clark (b) (4)	29 Sep 2020 16:49:35

**US3682040**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	29 Sep 2020 16:49:35
	(b) (4)	

**US3682040**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	Jesse Clark (b) (4)	29 Sep 2020 16:42:07



**US3682040**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'I'	System	29 Sep 2020 16:42:07

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	Jesse Clark (b) (4)	29 Sep 2020 16:42:20

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '29 Sep 2020'	Jesse Clark (b) (4)	29 Sep 2020 16:42:20

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Clinic (Clinic)'	Jesse Clark (b) (4)	29 Sep 2020 16:42:20

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'VISIT2'	System	29 Sep 2020 16:42:20

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08



**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '09:40'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '29 Sep 2020 09:40'	System	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '69'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'bpm'	System	29 Sep 2020 18:02:08

US3682040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '14'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08



**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'breaths/min'	System	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '130'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'mmHg'	System	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '79'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'mmHg'	System	29 Sep 2020 18:02:08

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16



**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16



**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 18:02:16

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	29 Sep 2020 16:42:47
	(b) (4)	

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '29 Sep 2020'	Jesse Clark (b) (4)	29 Sep 2020 16:42:47

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	29 Sep 2020 16:50:57
	(b) (4)	



**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Jesse Clark (b) (4)	29 Sep 2020 16:50:57

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Participant with varicella zoster eruption in trigeminal nerve distribution. Due to concern for reactivation following immunization, study product withheld.'	Jesse Clark (b) (4)	29 Sep 2020 16:50:57

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 16:50:57

US3682040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:04:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	29 Sep 2020 16:50:57
	(b) (4)	

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	29 Sep 2020 16:50:57
	(b) (4)	

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 16:50:57

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:50:57

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 16:50:57



**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 16:50:57

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:23:37

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:23:37

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '09:44'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:23:37

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '29 Sep 2020 09:44'	System	29 Sep 2020 18:23:37

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 23:04:14**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:23:53

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Sep 2020 18:23:53

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:23:53



**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '09:48'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:23:53

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '29 Sep 2020 09:48'	System	29 Sep 2020 18:23:53

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Sep 2020 18:23:53

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:23:53

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:23:53

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered empty.	System	29 Sep 2020 18:23:53

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:33

**US3682040**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '1'	System	29 Sep 2020 18:02:33



**US3682040**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 22:33:12

**US3682040**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered '6 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 22:33:12

**US3682040**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 22:33:12

**US3682040**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 22:33:12

**US3682040**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:12:03
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 22:33:16

**US3682040**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'I'	System	06 Oct 2020 22:33:16

**US3682040**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Oct 2020 22:52:27

**US3682040**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered '13 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Oct 2020 22:52:27



**US3682040**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Oct 2020 22:52:27

**US3682040**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	13 Oct 2020 22:52:27

**US3682040**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Oct 2020 22:52:32

**US3682040**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'I'	System	13 Oct 2020 22:52:32

**US3682040**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	20 Oct 2020 23:01:10

**US3682040**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered '20 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	20 Oct 2020 23:01:10

**US3682040**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	20 Oct 2020 23:01:10

**US3682040**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	20 Oct 2020 23:01:10



**US3682040**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:03:45
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	20 Oct 2020 23:01:14

**US3682040**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'I'	System	20 Oct 2020 23:01:14

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	27 Oct 2020 20:17:50

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '27 Oct 2020'	(b) (4) Timothy Hall (b) (4)	27 Oct 2020 20:17:50

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Clinic (Clinic)'	(b) (4) Timothy Hall (b) (4) (b) (4)	27 Oct 2020 20:17:50

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User entered 'VISIT3'	System	27 Oct 2020 20:17:50

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02



**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '13:11'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User entered '27 Oct 2020 13:11'	System	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '76'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User entered 'bpm'	System	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '14'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02



**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User entered 'breaths/min'	System	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '138'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User entered 'mmHg'	System	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '92'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09
User entered 'mmHg'	System	27 Oct 2020 21:45:02

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:09

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	27 Oct 2020 20:25:38



**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '27 Oct 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	27 Oct 2020 20:25:38

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:42:29

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:42:29

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered '13:35'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:42:29

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered '27 Oct 2020 13:35'	System	27 Oct 2020 22:42:29

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:05:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:45:08

**US3682040**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'I'	System	27 Oct 2020 21:45:08

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 64'	System	01 Sep 2020 17:59:09



**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-01T19:46:09', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '14fa476b-c3f9-4738-a9d0-677a07d8286c'	System	02 Nov 2020 03:46:30
User entered 'No (N)'	System	02 Nov 2020 03:46:30

US3682040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

Have you been exposed to someone with 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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-01T19:46:13', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '14fa476b-c3f9-4738-a9d0-677a07d8286c'	System	02 Nov 2020 03:46:30
User entered 'No (N)'	System	02 Nov 2020 03:46:30

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-01T19:46:28', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '14fa476b-c3f9-4738-a9d0-677a07d8286c'	System	02 Nov 2020 03:46:30
User entered '01 Nov 2020 19:46:28'	System	02 Nov 2020 03:46:30

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 71'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-09T17:02:51', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '54ca639e-bfb2-434c-bb61-ce5dbdf9139e'	System	10 Nov 2020 01:03:14
User entered 'No (N)'	System	10 Nov 2020 01:03:14

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Have you been exposed to someone with 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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-09T17:03:05', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '54ca639e-bfb2-434c-bb61-ce5dbdf9139e'	System	10 Nov 2020 01:03:14
User entered 'No (N)'	System	10 Nov 2020 01:03:14



**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-09T17:03:12', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '54ca639e-bfb2-434c-bb61-ce5dbdf9139e' User entered '09 Nov 2020 17:03:12'	System	10 Nov 2020 01:03:14
	System	10 Nov 2020 01:03:14

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered 'Day 78'	System	01 Sep 2020 17:59:09

US3682040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:04:14

[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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-15T07:22:11', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'd3bfcd87-165b-4d42-87ef-b54d1bb6d58c'	System	15 Nov 2020 15:22:59
User entered 'No (N)'	System	15 Nov 2020 15:22:59

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Have you been exposed to someone with 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)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-15T07:22:46', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'd3bfcd87-165b-4d42-87ef-b54d1bb6d58c'	System	15 Nov 2020 15:22:59
User entered 'No (N)'	System	15 Nov 2020 15:22:59

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-15T07:22:53', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'd3bfcd87-165b-4d42-87ef-b54d1bb6d58c'	System	15 Nov 2020 15:22:59
User entered '15 Nov 2020 07:22:53'	System	15 Nov 2020 15:22:59

**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 17:59:09



**US3682040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:40:44
Data entry locked.	System	01 Sep 2020 17:59:09
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 17:59:09

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2020-11-22T16:14:32', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '016a2144-9f28-4db3-bc90-f096a7a51d1b'	System	23 Nov 2020 00:14:47
User entered 'No (N)'	System	23 Nov 2020 00:14:47

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2020-11-22T16:14:39', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '016a2144-9f28-4db3-bc90-f096a7a51d1b'	System	23 Nov 2020 00:14:47
User entered 'No (N)'	System	23 Nov 2020 00:14:47

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-22T16:14:43', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '016a2144-9f28-4db3-bc90-f096a7a51d1b' User entered '22 Nov 2020 16:14:43'	System	23 Nov 2020 00:14:47

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2020-11-26T06:19:05', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '67cd5b56-26c9-46eb-86e3-7438b313afdf'	System	26 Nov 2020 14:19:32
User entered 'No (N)'	System	26 Nov 2020 14:19:32

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2020-11-26T06:19:15', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '67cd5b56-26c9-46eb-86e3-7438b313afdf'	System	26 Nov 2020 14:19:32
User entered 'No (N)'	System	26 Nov 2020 14:19:32

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-11-26T06:19:28', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '67cd5b56-26c9-46eb-86e3-7438b313afdf'	System	26 Nov 2020 14:19:32
User entered '26 Nov 2020 06:19:28'	System	26 Nov 2020 14:19:32

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2020-12-06T12:20:02', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '85e606d5-5194-4ed2-bed0-f8a48346bd28'	System	06 Dec 2020 20:20:22
User entered 'No (N)'	System	06 Dec 2020 20:20:22

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2020-12-06T12:20:08', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '85e606d5-5194-4ed2-bed0-f8a48346bd28'	System	06 Dec 2020 20:20:22
User entered 'No (N)'	System	06 Dec 2020 20:20:22



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-12-06T12:20:17', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '85e606d5-5194-4ed2-bed0-f8a48346bd28'	System	06 Dec 2020 20:20:22
User entered '06 Dec 2020 12:20:17'	System	06 Dec 2020 20:20:22

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2020-12-13T14:28:27', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '3e0407ab-680e-4e3a-a69a-eb6a59af2069'	System	13 Dec 2020 22:28:55
User entered 'No (N)'	System	13 Dec 2020 22:28:55

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2020-12-13T14:28:46', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '3e0407ab-680e-4e3a-a69a-eb6a59af2069'	System	13 Dec 2020 22:28:55
User entered 'No (N)'	System	13 Dec 2020 22:28:55

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-12-13T14:28:51', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '3e0407ab-680e-4e3a-a69a-eb6a59af2069'	System	13 Dec 2020 22:28:55
User entered '13 Dec 2020 14:28:51'	System	13 Dec 2020 22:28:55

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2020-12-17T00:11:19', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '84c902b3-b61b-4f51-8d46-f62cb04e8be2'	System	17 Dec 2020 08:11:45
User entered 'No (N)'	System	17 Dec 2020 08:11:45

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2020-12-17T00:11:38', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '84c902b3-b61b-4f51-8d46-f62cb04e8be2'	System	17 Dec 2020 08:11:45
User entered 'No (N)'	System	17 Dec 2020 08:11:45

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-12-17T00:11:42', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '84c902b3-b61b-4f51-8d46-f62cb04e8be2'	System	17 Dec 2020 08:11:45
User entered '17 Dec 2020 00:11:42'	System	17 Dec 2020 08:11:45

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2020-12-24T00:01:23', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'b1e106c1-713d-4001-bcf6-387a7afd573d'	System	24 Dec 2020 08:02:02
User entered 'No (N)'	System	24 Dec 2020 08:02:02

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2020-12-24T00:01:33', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'b1e106c1-713d-4001-bcf6-387a7afd573d'	System	24 Dec 2020 08:02:02
User entered 'Yes (Y)'	System	24 Dec 2020 08:02:02

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please 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 (a22198f60cd69681)', Time: '2020-12-24T00:01:45', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'b1e106c1-713d-4001-bcf6-387a7afd573d'	System	24 Dec 2020 08:02:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Dec 2020 08:02:02

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-12-24T00:01:53', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'b1e106c1-713d-4001-bcf6-387a7afd573d'	System	24 Dec 2020 08:02:02
User entered '24 Dec 2020 00:01:53'	System	24 Dec 2020 08:02:02

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2020-12-31T18:48:19', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '8b75690a-a29f-4acc-9719-328b047bd12a'	System	01 Jan 2021 02:49:17
User entered 'Yes (Y)'	System	01 Jan 2021 02:49:17



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2020-12-31T18:48:34', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '8b75690a-a29f-4acc-9719-328b047bd12a'	System	01 Jan 2021 02:49:17
User entered 'Yes (Y)'	System	01 Jan 2021 02:49:17

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Please 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 (a22198f60cd69681)', Time: '2020-12-31T18:48:39', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '8b75690a-a29f-4acc-9719-328b047bd12a'	System	01 Jan 2021 02:49:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 02:49:17

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2020-12-31T18:48:54', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '8b75690a-a29f-4acc-9719-328b047bd12a'	System	01 Jan 2021 02:49:17
User entered 'No (N)'	System	01 Jan 2021 02:49:17

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2020-12-31T18:49:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '8b75690a-a29f-4acc-9719-328b047bd12a'	System	01 Jan 2021 02:49:17
User entered 'No (N)'	System	01 Jan 2021 02:49:17

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2020-12-31T18:49:07', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '8b75690a-a29f-4acc-9719-328b047bd12a'	System	01 Jan 2021 02:49:17
User entered '31 Dec 2020 18:49:07'	System	01 Jan 2021 02:49:17

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2021-01-07T08:08:41', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '48562140-a220-4111-ab3c-49a9845d0b0b'	System	07 Jan 2021 16:09:20
User entered 'Yes (Y)'	System	07 Jan 2021 16:09:20

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2021-01-07T08:08:49', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '48562140-a220-4111-ab3c-49a9845d0b0b'	System	07 Jan 2021 16:09:20
User entered 'No (N)'	System	07 Jan 2021 16:09:20

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2021-01-07T08:08:59', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '48562140-a220-4111-ab3c-49a9845d0b0b'	System	07 Jan 2021 16:09:20
User entered 'No (N)'	System	07 Jan 2021 16:09:20

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2021-01-07T08:09:14', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '48562140-a220-4111-ab3c-49a9845d0b0b'	System	07 Jan 2021 16:09:20
User entered 'No (N)'	System	07 Jan 2021 16:09:20

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2021-01-07T08:09:17', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '48562140-a220-4111-ab3c-49a9845d0b0b'	System	07 Jan 2021 16:09:20
User entered '07 Jan 2021 08:09:17'	System	07 Jan 2021 16:09:20

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2021-01-14T00:01:25', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'ed302120-00c5-42b0-8c03-4c86e47c787f'	System	14 Jan 2021 08:02:04
User entered 'No (N)'	System	14 Jan 2021 08:02:04

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2021-01-14T00:01:51', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'ed302120-00c5-42b0-8c03-4c86e47c787f'	System	14 Jan 2021 08:02:04
User entered 'No (N)'	System	14 Jan 2021 08:02:04

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2021-01-14T00:01:59', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'ed302120-00c5-42b0-8c03-4c86e47c787f'	System	14 Jan 2021 08:02:04
User entered '14 Jan 2021 00:01:59'	System	14 Jan 2021 08:02:04

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (a22198f60cd69681)', Time: '2021-01-21T19:18:16', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e890364e-e0de-4343-a188-84aa371957e8'	System	22 Jan 2021 03:18:30
User entered 'No (N)'	System	22 Jan 2021 03:18:30

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (a22198f60cd69681)', Time: '2021-01-21T19:18:24', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e890364e-e0de-4343-a188-84aa371957e8'	System	22 Jan 2021 03:18:30
User entered 'No (N)'	System	22 Jan 2021 03:18:30



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a22198f60cd69681)', Time: '2021-01-21T19:18:28', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e890364e-e0de-4343-a188-84aa371957e8'	System	22 Jan 2021 03:18:30
User entered '21 Jan 2021 19:18:28'	System	22 Jan 2021 03:18:30

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-02-01T12:56:01', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'f782b973-b217-4906-b0e8-6385a1040edc'	System	01 Feb 2021 20:59:06
User entered 'No (N)'	System	01 Feb 2021 20:59:06

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-02-01T12:56:06', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'f782b973-b217-4906-b0e8-6385a1040edc'	System	01 Feb 2021 20:59:06
User entered 'No (N)'	System	01 Feb 2021 20:59:06

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-02-01T12:56:08', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'f782b973-b217-4906-b0e8-6385a1040edc'	System	01 Feb 2021 20:59:06
User entered '01 Feb 2021 12:56:08'	System	01 Feb 2021 20:59:06

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-02-05T06:40:14', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e9f00628-1d18-4265-98b8-f170133bb6cd'	System	05 Feb 2021 14:40:27
User entered 'No (N)'	System	05 Feb 2021 14:40:27

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-02-05T06:40:20', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e9f00628-1d18-4265-98b8-f170133bb6cd'	System	05 Feb 2021 14:40:27
User entered 'No (N)'	System	05 Feb 2021 14:40:27

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-02-05T06:40:24', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e9f00628-1d18-4265-98b8-f170133bb6cd' User entered '05 Feb 2021 06:40:24'	System	05 Feb 2021 14:40:27
	System	05 Feb 2021 14:40:27

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-02-11T22:54:47', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e8e49468-1b82-4ce9-bd64-bfd5bb6233ea'	System	12 Feb 2021 06:55:05
User entered 'No (N)'	System	12 Feb 2021 06:55:05

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-02-11T22:54:50', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e8e49468-1b82-4ce9-bd64-bfd5bb6233ea'	System	12 Feb 2021 06:55:05
User entered 'No (N)'	System	12 Feb 2021 06:55:05

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-02-11T22:55:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e8e49468-1b82-4ce9-bd64-bfd5bb6233ea' User entered '11 Feb 2021 22:55:00'	System	12 Feb 2021 06:55:05
	System	12 Feb 2021 06:55:05

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-02-18T00:01:23', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'd55661ed-9398-4bec-8006-cc07d0b1bad5'	System	18 Feb 2021 08:01:39
User entered 'No (N)'	System	18 Feb 2021 08:01:39

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-02-18T00:01:32', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'd55661ed-9398-4bec-8006-cc07d0b1bad5'	System	18 Feb 2021 08:01:39
User entered 'No (N)'	System	18 Feb 2021 08:01:39



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-02-18T00:01:35', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'd55661ed-9398-4bec-8006-cc07d0b1bad5'	System	18 Feb 2021 08:01:39
User entered '18 Feb 2021 00:01:35'	System	18 Feb 2021 08:01:39

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-02-25T21:15:39-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '1d0c98b8-c720-4e97-89ec-d0da8207b3eb' User entered 'No (N)'	System	26 Feb 2021 05:15:56
	System	26 Feb 2021 05:15:56

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-02-25T21:15:44-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '1d0c98b8-c720-4e97-89ec-d0da8207b3eb'	System	26 Feb 2021 05:15:56
User entered 'No (N)'	System	26 Feb 2021 05:15:56

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-02-25T21:15:53-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '1d0c98b8-c720-4e97-89ec-d0da8207b3eb' User entered '25 Feb 2021 21:15:53'	System	26 Feb 2021 05:15:56
	System	26 Feb 2021 05:15:56

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-03-08T08:29:42-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '04f3f75f-2337-4132-a2b9-893f5b70c47d'	System	08 Mar 2021 16:29:53
User entered 'No (N)'	System	08 Mar 2021 16:29:53

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-03-08T08:29:46-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '04f3f75f-2337-4132-a2b9-893f5b70c47d'	System	08 Mar 2021 16:29:53
User entered 'No (N)'	System	08 Mar 2021 16:29:53

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-03-08T08:29:49-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '04f3f75f-2337-4132-a2b9-893f5b70c47d'	System	08 Mar 2021 16:29:53
User entered '08 Mar 2021 08:29:49'	System	08 Mar 2021 16:29:53

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-03-12T17:11:28-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'cff255ee-861a-4628-8274-5088e19f3542'	System	13 Mar 2021 01:11:44
User entered 'No (N)'	System	13 Mar 2021 01:11:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-03-12T17:11:37-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'cff255ee-861a-4628-8274-5088e19f3542'	System	13 Mar 2021 01:11:44
User entered 'No (N)'	System	13 Mar 2021 01:11:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-03-12T17:11:41-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'cff255ee-861a-4628-8274-5088e19f3542'	System	13 Mar 2021 01:11:44
User entered '12 Mar 2021 17:11:41'	System	13 Mar 2021 01:11:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-03-19T14:30:39-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '4d7d2879-a5ff-466a-8c1f-5299fe5a0f20' User entered 'No (N)'	System	19 Mar 2021 21:30:52
	System	19 Mar 2021 21:30:52

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-03-19T14:30:42-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '4d7d2879-a5ff-466a-8c1f-5299fe5a0f20'	System	19 Mar 2021 21:30:52
User entered 'No (N)'	System	19 Mar 2021 21:30:52



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-03-19T14:30:49-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '4d7d2879-a5ff-466a-8c1f-5299fe5a0f20' User entered '19 Mar 2021 14:30:49'	System	19 Mar 2021 21:30:52
	System	19 Mar 2021 21:30:52

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-03-26T18:24:11-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '225d5b8e-84c4-457b-aaf4-16df4161e99b'	System	27 Mar 2021 01:25:18
User entered 'No (N)'	System	27 Mar 2021 01:25:18

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-03-26T18:24:14-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '225d5b8e-84c4-457b-aaf4-16df4161e99b'	System	27 Mar 2021 01:25:18
User entered 'No (N)'	System	27 Mar 2021 01:25:18

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-03-26T18:24:22-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '225d5b8e-84c4-457b-aaf4-16df4161e99b' User entered '26 Mar 2021 18:24:22'	System	27 Mar 2021 01:25:18
	System	27 Mar 2021 01:25:18

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-04-08T05:21:52-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '5e3ea694-760f-4de1-b21b-d1818f957352'	System	08 Apr 2021 12:21:59
User entered 'No (N)'	System	08 Apr 2021 12:21:59

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-04-08T05:21:54-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '5e3ea694-760f-4de1-b21b-d1818f957352'	System	08 Apr 2021 12:21:59
User entered 'No (N)'	System	08 Apr 2021 12:21:59

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-04-08T05:21:57-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '5e3ea694-760f-4de1-b21b-d1818f957352'	System	08 Apr 2021 12:21:59
User entered '08 Apr 2021 05:21:57'	System	08 Apr 2021 12:21:59



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-04-19T14:45:45-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '263b9c5f-47bc-44dd-a532-57e4d69a7034'	System	19 Apr 2021 21:46:04
User entered 'No (N)'	System	19 Apr 2021 21:46:04

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-04-19T14:45:55-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '263b9c5f-47bc-44dd-a532-57e4d69a7034'	System	19 Apr 2021 21:46:04
User entered 'No (N)'	System	19 Apr 2021 21:46:04

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-04-19T14:45:58-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '263b9c5f-47bc-44dd-a532-57e4d69a7034'	System	19 Apr 2021 21:46:04
User entered '19 Apr 2021 14:45:58'	System	19 Apr 2021 21:46:04

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-04-22T05:58:28-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '919711fb-4b2b-4b53-b0d7-b0873e35f3a7'	System	22 Apr 2021 12:58:44
User entered 'No (N)'	System	22 Apr 2021 12:58:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-04-22T05:58:33-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '919711fb-4b2b-4b53-b0d7-b0873e35f3a7'	System	22 Apr 2021 12:58:44
User entered 'No (N)'	System	22 Apr 2021 12:58:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-04-22T05:58:37-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: '919711fb-4b2b-4b53-b0d7-b0873e35f3a7'	System	22 Apr 2021 12:58:44
User entered '22 Apr 2021 05:58:37'	System	22 Apr 2021 12:58:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[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 (4fc62156ac31230b)', Time: '2021-05-02T23:03:15-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e2de33df-4358-41dc-aea5-2e664db2f362'	System	03 May 2021 06:03:30
User entered 'No (N)'	System	03 May 2021 06:03:30



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

Have you been exposed to someone with 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 (4fc62156ac31230b)', Time: '2021-05-02T23:03:22-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e2de33df-4358-41dc-aea5-2e664db2f362'	System	03 May 2021 06:03:30
User entered 'No (N)'	System	03 May 2021 06:03:30

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-05-02T23:03:26-07:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'e2de33df-4358-41dc-aea5-2e664db2f362'	System	03 May 2021 06:03:30
User entered '02 May 2021 23:03:26'	System	03 May 2021 06:03:30

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:45:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:45:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:45:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:45:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:45:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:45:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:45:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:45:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:45:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:45:44

**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:45:44



**US3682040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:04:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:45:44
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:45:44

US3682040

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:04:14

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 18:43:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-03-08T08:29:57-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'a40f3610-5ff8-48a7-8180-f81d2949f3fd'	System	08 Mar 2021 16:30:10
User entered 'No (N)'	System	08 Mar 2021 16:30:10

**US3682040**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:43:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4fc62156ac31230b)', Time: '2021-03-08T08:30:03-08:00', User OID: 'PatientReportedOutcome (US3682040)', ODM File OID: 'a40f3610-5ff8-48a7-8180-f81d2949f3fd'	System	08 Mar 2021 16:30:10
User entered '08 Mar 2021 08:30:03'	System	08 Mar 2021 16:30:10

**US3682040**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:46:48

**US3682040**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
User entered '25 Nov 2020'	(b) (4) Mitchell Stern (b) (4)	25 Nov 2020 23:46:48

**US3682040**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:46:48

**US3682040**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:46:48

**US3682040**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:46:59



**US3682040**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:07:02
User entered 'I'	System	25 Nov 2020 23:46:59

**US3682040**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	28 Dec 2020 23:07:18

**US3682040**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '28 Dec 2020'	Mitchell Stern (b) (4)	28 Dec 2020 23:07:18

**US3682040**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	28 Dec 2020 23:07:18

**US3682040**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered empty.	Mitchell Stern (b) (4)	28 Dec 2020 23:07:18

**US3682040**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	28 Dec 2020 23:07:24

**US3682040**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:56
User entered 'I'	System	28 Dec 2020 23:07:24

**US3682040**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:37



**US3682040**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:37

**US3682040**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:37

**US3682040**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:37

**US3682040**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:42

**US3682040**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:56
User entered 'I'	System	27 Jan 2021 21:33:42

**US3682040**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	Jesse Clark (b) (4)	26 Feb 2021 22:43:56

**US3682040**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '26 Feb 2021'	Jesse Clark (b) (4)	26 Feb 2021 22:43:56

**US3682040**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Contact Made (CONTACT MADE)'	Jesse Clark (b) (4)	26 Feb 2021 22:43:56



**US3682040**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered empty.	Jesse Clark (b) (4)	26 Feb 2021 22:43:56

**US3682040**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	Jesse Clark (b) (4)	26 Feb 2021 22:44:03

**US3682040**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User entered '1'	System	26 Feb 2021 22:44:03

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:37:46

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '29 Mar 2021'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:37:46

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Clinic (Clinic)'	Schuyler Thomas (b) (4)	29 Mar 2021 21:37:46

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User entered 'VISIT4'	System	29 Mar 2021 21:37:46

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:39:56



**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '29 Mar 2021'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '13:58'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User entered '29 Mar 2021 13:58'	System	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '97.7' F	Schuyler Thomas (b) (4)	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered empty.	Schuyler Thomas (b) (4)	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '77'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User entered 'bpm'	System	29 Mar 2021 21:39:56



**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '16'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User entered 'breaths/min'	System	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '176'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User entered 'mmHg'	System	29 Mar 2021 21:39:56

US3682040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 06:51:32
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Schuyler Thomas (b) (4) (b) (4)	29 Mar 2021 21:40:03
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		29 Mar 2021 21:39:56
User entered '108'	Schuyler Thomas (b) (4) (b) (4)	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User entered 'mmHg'	System	29 Mar 2021 21:39:56

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57



**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:46:14

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '29 Mar 2021'	Schuyler Thomas (b) (4)	29 Mar 2021 21:46:14

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:57:40

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:57:40

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered '14:22'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:57:40

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User entered '29 Mar 2021 14:22'	System	31 Mar 2021 18:57:40

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:43:29
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	29 Mar 2021 21:46:31

**US3682040**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:57
User entered 'I'	System	29 Mar 2021 21:46:31



US3682040

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:04:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 04:33:36
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered 'Yes (Y)' reason for change: New Information	Jesse Clark (b) (4)	27 Apr 2021 20:39:20
Query 'Data is required. Please complete.' answered with 'data pending' (Site from System).	Mitchell Stern (b) (4)	27 Apr 2021 20:13:07
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:12:56
User entered empty; reason for change Data Entry Error	Mitchell Stern (b) (4)	27 Apr 2021 20:12:56
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	27 Apr 2021 20:08:34

**US3682040**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
	(b) (4)	
User entered '27 Apr 2021' reason for change: New Information	Jesse Clark (b) (4)	27 Apr 2021 20:39:20
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mitchell Stern (b) (4)	27 Apr 2021 20:12:56
	(b) (4)	
User entered '27 Apr 2021'	Mitchell Stern (b) (4)	27 Apr 2021 20:08:34
	(b) (4)	

**US3682040**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jesse Clark (b) (4)	27 Apr 2021 20:39:20
reason for change: New Information	(b) (4)	
User entered empty; reason for change Data Entry	Mitchell Stern (b) (4)	27 Apr 2021 20:12:56
Error	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	27 Apr 2021 20:08:34
	(b) (4)	

**US3682040**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	27 Apr 2021 20:08:34
	(b) (4)	

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	29 Apr 2021 16:33:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 04:33:31
User entered 'Yes (Y)' reason for change: New Information	Jesse Clark (b) (4) (b) (4)	27 Apr 2021 20:39:40
Query 'Data is required. Please complete.' answered with 'data pending' (Site from System).	Mitchell Stern (b) (4) (b) (4)	27 Apr 2021 20:13:24
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:13:16
User entered empty; reason for change Data Entry Error	Mitchell Stern (b) (4) (b) (4)	27 Apr 2021 20:13:16
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	27 Apr 2021 20:08:44

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**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 20:39:40
User entered empty.	System	27 Apr 2021 20:13:16
User entered 'I'	System	27 Apr 2021 20:08:44

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Folder: Covid-19 Assessment 24 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:04:14

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:43
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 17:59:29
User closed query 'Per email from (b) (6) (b) (6), filed in source, dated 24Dec2020- site is aware of subject reporting covid symptoms on 24Dec2020. Please verify and update accordingly' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:55:16
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:55:14
Query 'Per email from (b) (6), filed in source, dated 24Dec2020- site is aware of subject reporting covid symptoms on 24Dec2020. Please verify and update accordingly' answered with 'updated per source notes' (Site from CRA).	Mitchell Stern (b) (4) (b) (4)	07 Apr 2021 21:28:18
Signature has been broken.	Mitchell Stern (b) (4) (b) (4)	07 Apr 2021 21:26:21
User entered '24 Dec 2020' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	07 Apr 2021 21:26:21
User opened query 'Per email from (b) (6) (b) (6), filed in source, dated 24Dec2020- site is aware of subject reporting covid symptoms on 24Dec2020. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:08:29
Query 'Per email from (b) (6), filed in source, dated 24Dec2020- site is aware of subject reporting covid symptoms. Please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:07:43
User opened query 'Per email from (b) (6) (b) (6) filed in source, dated 24Dec2020- site is aware of subject reporting covid symptoms. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:01:53
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:58:55
User closed query 'This was not the first contact date per source document.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:43:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:45
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:42:53

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Folder: Covid-19 Assessment 24 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:04:14

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'This was not the first contact date per source document.' answered with 'reviewed updated' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:51:07
User entered '28 Dec 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Mar 2021 22:50:57
User opened query 'This was not the first contact date per source document.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:41:39
User closed query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:41:39
Query 'This is not in source document. Please verify and update accordingly.' answered with 'Entry corrected based on date COVID symptoms first reported.' (Site from CRA).	Jesse Clark (b) (4)	22 Feb 2021 22:52:23
User entered '24 Dec 2020' reason for change: Per Query Resolution	Jesse Clark (b) (4)	22 Feb 2021 22:52:04
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 23:46:17
User entered '28 Dec 2020'	Oladunni Adeyiga (b) (4)	28 Dec 2020 20:06:17



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Folder: Covid-19 Assessment 24 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:04:14

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:43
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:57:12
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 17:59:29
DataPoint Un-verified.	(b) (4)	
	Mitchell Stern (b) (4)	07 Apr 2021 21:26:21
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	07 Apr 2021 21:26:21
	(b) (4)	
User entered '12:12' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	07 Apr 2021 21:26:21
	(b) (4)	
User closed query 'This contact time is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:43:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:45
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
Query 'This contact time is not in source document. Please verify and update accordingly.' answered with 'updated accordingly' (Site from CRA).	Mitchell Stern (b) (4)	04 Mar 2021 00:46:51
	(b) (4)	
User opened query 'This contact time is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:40:14
User entered '09:30'	Oladunni Adeyiga (b) (4)	28 Dec 2020 20:06:17
	(b) (4)	

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:04:14**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:43
User entered '24 Dec 2020 12:12'	System	07 Apr 2021 21:26:21
User entered '28 Dec 2020 09:30'	System	03 Mar 2021 22:50:57
User entered '24 Dec 2020 09:30'	System	22 Feb 2021 22:52:04
User entered '28 Dec 2020 09:30'	System	28 Dec 2020 20:06:17

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:04:14**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:45
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:06:17

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:04:14**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:45
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Yes (Y)'	Oladunni Adeyiga (b) (4)	28 Dec 2020 20:06:17

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 1 (Day 1)'	(b) (4) Oladunni Adeyiga (b) (4)	28 Dec 2020 20:08:03

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:33
User entered '21 Dec 2020'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:35
User closed query 'Per CDM: Assessment Not Done is checked yet data is present for days 1 - 8. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:50:46
Query 'Per CDM: Assessment Not Done is checked yet data is present for days 1 - 8. Please review and reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:40:22
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:40:15
User opened query 'Per CDM: Assessment Not Done is checked yet data is present for days 1 - 8. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 15:43:59
User entered '1'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:40:15
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03



**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	22 Jan 2021 21:40:15
User entered empty.	System	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:40:15
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:44
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:45
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:47
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:49
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:53
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:55
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:47:59
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:48:04
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:48:54
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:48:56
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:49:05
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:49:08
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (1)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:49:37
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:49:47
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:49:49
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:49:51
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:08:03

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 2 (Day 2)'	(b) (4) Oladunni Adeyiga (b) (4)	28 Dec 2020 20:10:10

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:50:40
User entered '22 Dec 2020'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:50:54
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:40:41
User entered '1'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:50:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:40:41
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	22 Jan 2021 21:40:41
User entered empty.	System	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:50:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:40:41
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:51:03
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:51:06
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:51:08
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:51:10
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:42:51
User closed query 'This is none in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:42:47
Query 'This is none in source document. Please verify and update accordingly.' answered with 'Entry confirmed in source documentation.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 22:04:09
User opened query 'This is none in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 23:52:09
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 23:51:24
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 23:51:13
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:43:00
User closed query 'This is none in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:42:58
Query 'This is none in source document. Please verify and update accordingly.' answered with 'Entry confirmed in source documentation.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 22:04:14
User opened query 'This is none in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 23:52:28
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:52:50
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:53:01
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:53:06
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:53:09
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:43:10
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 23:53:15
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 23:53:12
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:53:21
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:53:34
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:53:36
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:53:37
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:53:39
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:10:10



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**Form: Symptom Log (3)**

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 3 (Day 3)'	(b) (4) Oladunni Adeyiga (b) (4)	28 Dec 2020 20:12:06

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:55:49
User entered '23 Dec 2020'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:55:53
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:05
User entered '1'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:05
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	22 Jan 2021 21:41:05
User entered empty.	System	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:05
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:37
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:48
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:40
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:46
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:43
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:45
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (3)**

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:55
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:56:57
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:00
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:03
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06



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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (3)**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:08
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:11
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (3)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:14
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:16
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:18
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:22
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:12:06

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 4 (Day 4)'	(b) (4) Oladunni Adeyiga (b) (4)	28 Dec 2020 20:13:38

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:47
User entered '24 Dec 2020'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38



**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:50
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:18
User entered '1'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:18
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	22 Jan 2021 21:41:18
User entered empty.	System	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:18
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:57
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:57:59
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:04
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:07
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38



US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:09
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:11
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:13
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:16
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:23
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:25
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:31
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:37
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:42
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:46
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:49
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:58:52
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:13:38

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 5 (Day 5)'	(b) (4) Oladunni Adeyiga (b) (4)	28 Dec 2020 20:15:59

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:29
User entered '25 Dec 2020'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:31
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:34
User entered '1'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:34
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59



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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	22 Jan 2021 21:41:34
User entered empty.	System	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:34
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:36
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:38
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:47
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:49
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:51
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:52
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:01:54
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:01
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:15
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:20
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:24
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:26
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:30
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:32
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:34
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:36
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:15:59

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 6 (Day 6)'	(b) (4) Oladunni Adeyiga (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:52
User entered '26 Dec 2020'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:54
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:50
User entered '1'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:50
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	22 Jan 2021 21:41:50
User entered empty.	System	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:02:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:41:50
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:07
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:10
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:16
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:18
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:20
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:43:52
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:22
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:25
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:45
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:48
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:52
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:55
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:03:58
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:00
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:02
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:04
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:17:37



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**Form: Symptom Log (7)**

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 7 (Day 7)'	(b) (4) Oladunni Adeyiga (b) (4)	28 Dec 2020 20:19:07

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:22
User entered '27 Dec 2020'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (7)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:24
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:42:04
User entered '1'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:42:04
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	22 Jan 2021 21:42:04
User entered empty.	System	28 Dec 2020 20:19:07

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Form: Symptom Log (7)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:42:04
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:30
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:33
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07



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Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:37
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:39
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:42
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:49
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (7)**

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:51
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:04:53
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (7)**

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:05:04
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (7)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:05:09
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07



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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:05:11
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:05:13
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:05:18
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:05:20
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:05:22
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:05:24
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:19:07

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 8 (Day 8)'	(b) (4) Oladunni Adeyiga (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:06:01
User entered '28 Dec 2020'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42



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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:06:06
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:42:18
User entered '1'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'This was done per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:47:31
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:47:26
Query 'This was done per source document. Please verify and update accordingly.' answered with 'Entry corrected.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 22:05:17
User entered '98' reason for change: Per Query Resolution	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 22:05:08
User opened query 'This was done per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:06:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:42:18
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	22 Jan 2021 21:42:18
User entered empty.	System	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:47:40
User closed query 'This was done per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:47:37
Query 'This was done per source document. Please verify and update accordingly.' answered with 'Entry corrected.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 22:05:21
User entered '98.6' F reason for change: Per Query Resolution	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 22:05:08
User opened query 'This was done per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:42:18
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:07
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:20
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:18
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:22
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:24
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:26
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:29
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (8)**

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:31
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:34
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (8)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:37
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:40
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:43
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42



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**Form: Symptom Log (8)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:48
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Form: Symptom Log (8)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:50
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:53
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (8)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:07:54
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	28 Dec 2020 20:20:42

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Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 9 (Day 9)'	(b) (4) Timothy Hall (b) (4)	29 Dec 2020 23:46:43

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:08:30
User entered '29 Dec 2020'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:08:33
User entered '0'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:08:37
User entered '98'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43



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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:08:40
User entered '98.4' F	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:08:43
User entered 'Moderate (Moderate)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:08:46
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:08:48
User entered 'Mild (Mild)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:08:54
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:00
User entered 'Moderate (Moderate)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:01
User entered 'Moderate (Moderate)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43



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Form: Symptom Log (9)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:03
User entered 'Moderate (Moderate)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:12
User entered 'Severe (Severe)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:14
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Form: Symptom Log (9)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:16
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Form: Symptom Log (9)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:21
User entered 'Mild (Mild)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:25
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:28
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43



US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:32
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:34
User entered 'Moderate (Moderate)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:46:43

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 05:06:14

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:56
User entered '30 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 05:06:14

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:09:59
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 05:06:14

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:01
User closed query 'Per CDM : It appears data is missing for day 10. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:55:17
Query 'Per CDM : It appears data is missing for day 10. Please review and update accordingly.' answered with 'data update complete' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:28:14
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User opened query 'Per CDM : It appears data is missing for day 10. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 15:44:53
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	22 Jan 2021 21:28:03
User entered empty.	System	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:03
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14



US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:06
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:11
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:28
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:32
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:35
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:47
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:04:14**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:10:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:11:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:11:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:11:32
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:28:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 05:06:14



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:11:43
User entered '31 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

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Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:11:45
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:12:41
User entered '99'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:12:43
User entered '98.0' F	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:12:46
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:12:49
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35



US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:12:51
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:12:54
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:12:56
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:12:59
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:04:14**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:02
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:04
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:08
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:10
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35



US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:13
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:16
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:04:14**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:18
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:20
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:22
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:24
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:36
User entered '1 Jan 2021'	(b) (4), (b) (6)	04 Jan 2021 05:08:35



**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:37
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:40
User entered '99'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User entered '%'	System	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:42
User entered '97.5' F	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:48
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:50
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:52
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:54
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35



US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:56
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:57
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:13:59
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:14:01
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:14:03
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:14:05
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:14:07
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:14:30
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35



US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:14:33
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:14:35
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:14:38
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:14:41
User entered 'None (None)'	(b) (4), (b) (6)	04 Jan 2021 05:08:35

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:55:47
User entered '28 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 22:35:57

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:55:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 22:35:57

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:04:14

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:55:47
User closed query 'Per CDM: Response noted. However please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:22:24
Query 'Per CDM: Response noted. However please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE noted' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:31:40
User opened query 'Per CDM: Response noted. However please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 11:29:02
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 11:27:08
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'yes' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 22:36:04
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	30 Dec 2020 22:35:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 22:35:57

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:55:47
User entered '28 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 22:35:57



**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:55:47
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	30 Dec 2020 22:35:57

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:55:47
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 22:35:57

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:55:47
User entered 'No (N)'	(b) (4), (b) (6)	30 Dec 2020 22:35:57

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:55:47
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 22:35:57

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:55:47
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 22:35:57

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:56
User entered 'I'	System	30 Dec 2020 22:35:57

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:04:14

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:16:22
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 21:29:02

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:04:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:16:22
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 21:29:02



US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:04:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:16:22
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 21:29:02

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:04:14

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:16:22
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 21:29:02

US3682040

Folder: Covid-19 Assessment 24 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:04:14

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:16:22
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 21:29:02

**US3682040**

**Folder: Covid-19 Assessment 24 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:03
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[Heart Rate](#)

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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

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[Oxygen Saturation](#)

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

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[PaO2](#)

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[Did the subject have Respiratory failure?](#)

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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[High-Flow Oxygen?](#)

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[Non-Invasive Ventilation?](#)

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[Mechanical Ventilation?](#)

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[ECMO?](#)

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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

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[Evidence of Shock Requires  
Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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User entered empty.	(b) (4), (b) (6)	22 Jan 2021 21:29:02



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Folder: Covid-19 Assessment 24 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:04:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:16:22
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 21:29:02

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:04:14

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:38:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:00:01
User closed query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 18:59:51
Query 'This is not in source document. Please verify and update accordingly.' answered with 'Documentation of contact included in Study Call Log. Late progress note entered in chart to reflect contact.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 22:58:43
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 23:20:36
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 25NOV2020 is reported under Illness Visit Day1 visit in PPD Central lab, however the same is missing in EDC under Covid Diagnostic Test Visit for the same date. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	09 Dec 2020 11:58:22
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 25NOV2020 is reported under Illness Visit Day1 visit in PPD Central lab, however the same is missing in EDC under Covid Diagnostic Test Visit for the same date. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:01:07
' answered with 'updated' (Site from DM).		

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Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:04:14

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 25NOV2020 is reported under Illness Visit Day1 visit in PPD Central lab, however the same is missing in EDC under Covid Diagnostic Test Visit for the same date. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.  ' (Site from DM). User entered '24 Nov 2020'	(b) (4), (b) (6) [REDACTED] [REDACTED]	07 Dec 2020 04:03:54
	(b) (4), (b) (6) [REDACTED]	25 Nov 2020 22:26:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:04:14

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:38:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:24:04
User closed query 'Unable to locate this contact in source document. Please provide source document for this.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:23:17
Query 'Unable to locate this contact in source document. Please provide source document for this.' answered with 'date and time documented in safety call log.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:39:21
User opened query 'Unable to locate this contact in source document. Please provide source document for this.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 22:01:21
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 22:01:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'reviewed and updated' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:37:51
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 22:37:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 22:37:34
User entered '16:04' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 22:37:34
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 21:35:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 21:35:29
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:02:51
User entered '16:00'	(b) (4), (b) (6)	25 Nov 2020 22:26:26

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:04:14**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:38:52
User entered '24 Nov 2020 16:04'	System	03 Mar 2021 22:37:34
User entered empty.	System	03 Mar 2021 21:35:29
User entered '24 Nov 2020 16:00'	System	25 Nov 2020 22:26:26

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:04:14**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:38:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:02:58
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	25 Nov 2020 22:26:26

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:04:14**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:38:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:02:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 22:26:26

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 1 (Day 1)'	Mitchell Stern (b) (4)	25 Nov 2020 23:58:14



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:22:23
User entered '22 Nov 2020'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:22:26
User entered '0'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:22:28
User closed query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 - 3. If not collected , please consider recording Not Done.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:56:31
Query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 - 3. If not collected , please consider recording Not Done.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:15:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:15:06
User opened query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 - 3. If not collected , please consider recording Not Done.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 15:39:18
User entered empty.	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User entered '%'	System	22 Jan 2021 21:15:06
User entered empty.	System	25 Nov 2020 23:58:14

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:22:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:15:06
User entered empty.	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:22:41
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:22:43
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:22:47
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:22:58
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:01
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:03
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:06
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:07
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:12
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:14
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:16
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:18
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:20
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:22
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:25
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:27
User entered 'Mild (Mild)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:58:14

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 2 (Day 2)'	Mitchell Stern (b) (4)	25 Nov 2020 23:59:44

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:41
User entered '23 Nov 2020'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:44
User entered '0'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:15:51
User entered empty.	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User entered '%'	System	22 Jan 2021 21:15:51
User entered empty.	System	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:15:51
User entered empty.	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:54
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:55
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:23:58
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:06
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:08
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:10
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:14
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:16
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:18
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:20
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:22
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:25
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:27
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:32
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:41
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:44
User entered 'Mild (Mild)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:59:44

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 3 (Day 3)'	(b) (4) Mitchell Stern (b) (4)	26 Nov 2020 00:00:50

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:56
User entered '24 Nov 2020'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:24:58
User entered '0'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:19:02
User entered empty.	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User entered '%'	System	22 Jan 2021 21:19:02
User entered empty.	System	26 Nov 2020 00:00:50



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:19:02
User entered empty.	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:09
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:11
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:13
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:16
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:18
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:27
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:36
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:38
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:40
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:42
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:47
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:49
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:51
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:52
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:54
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50



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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:25:57
User entered 'Mild (Mild)'	Mitchell Stern (b) (4) (b) (4)	26 Nov 2020 00:00:50

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:18
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 04:09:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 04:09:40
User entered '25 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 04:09:40
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 04:01:20
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:20
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:21
User closed query 'Per CDM : It appears data is missing for day 4. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:58:25
Query 'Per CDM : It appears data is missing for day 4. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:16:48
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:16:41
User opened query 'Per CDM : It appears data is missing for day 4. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 15:41:05
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User entered '%'	System	22 Jan 2021 21:16:41
User entered empty.	System	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:24
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:17:08
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:51
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:26:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:02
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:06
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:09
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20



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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:11
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:28
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:27:31
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 21:18:22
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 04:01:20

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 04:02:39



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:01
User entered '26 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:03
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:29
User entered '98'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User entered '%'	System	30 Nov 2020 04:02:39

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:31
User entered '97.8' F	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:35
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:40
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:42
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:46
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:49
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:51
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:28:56
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:29:00
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:29:02
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:29:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39



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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:29:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:29:53
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:29:57
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:30:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:30:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Nov 2020 04:02:39

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:31:56
User entered '27 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:31:59
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 04:04:28



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:11
User entered '97'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User entered '%'	System	30 Nov 2020 04:04:28

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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:14
User entered '100.3' F	(b) (4), (b) (6)	30 Nov 2020 04:04:28

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:18
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:25
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:27
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:30
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:35
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:37
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:40
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:45
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:47
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:51
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:53
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:32:56
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:33:24
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:33:27
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:33:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:33:35
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:04:28

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:21
User entered '28 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:24
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:27
User entered '96'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User entered '%'	System	30 Nov 2020 04:06:13



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:33
User entered '98.7' F	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:38
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:44
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:46
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:49
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:52
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:57
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:34:59
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:02
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:05
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:08
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:11
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:21
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:28
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:38
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:06:13

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:53
User entered '29 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:35:55
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:12
User entered '99'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User entered '%'	System	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:14
User entered '98.8' F	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:19
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:22
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:31
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 23:36:27
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 23:36:23
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:48
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:36:57
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:37:29
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:37:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:37:35
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:37:37
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:37:39
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:37:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:37:44
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 04:07:43

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Day 9 (Day 9)'	Jesse Clark (b) (4)	01 Dec 2020 00:33:26



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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:12
User entered '30 Nov 2020'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:14
User entered '0'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:16
User entered '93'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:04:14**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User entered '%'	System	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:19
User entered '98.6' F	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:22
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:23
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:25
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26



US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:27
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:32
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:35
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:40
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:42
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:44
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:46
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26



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Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:48
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:51
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:38:54
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:39:03
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:04:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:01
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:39:05
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	01 Dec 2020 00:33:26

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:11
User entered '25 Nov 2020'	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:00:57

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:13
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:00:57

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:15
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:00:57



**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:22
User entered '25 Nov 2020'	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:00:57

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:18
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:00:57

US3682040

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:04:14

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:24
User entered empty.	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:00:57

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:26
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:00:57

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Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:04:14

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:29
User entered empty.	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:00:57

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:31
User entered empty.	Susan Reed (b) (4) (b) (4)	07 Dec 2020 19:00:57

**US3682040**

**Folder: Covid-19 Assessment 24 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:04:14**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:07
User entered '0'	System	07 Dec 2020 19:00:57

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07



**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:25:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:25:07
User entered '27 Nov 2020'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:31:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:31:08
User entered '29 Nov 2020'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:35:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 01:01:46
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

US3682040

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:04:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:35:49
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 04:47:44
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Specimen resulted out on 12/10/2020 Accession number 1F60ET0' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 23:34:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 05:15:03
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 01:01:46
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 00:57:07



**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:36:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:36:11
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:36:16
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:36:24
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:36:30
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07



**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:36:32
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:36:37
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:41
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:36:40
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 00:57:07

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:58:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:58:32
User entered '30 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	30 Dec 2020 17:43:08



US3682040

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:04:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:58:32
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 00:52:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 00:52:48
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	05 Jan 2021 00:52:48
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 17:43:08
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:58:32
Query 'Per GCL Lab Recon: Saliva: Sample dated 01JAN2021 for Day 5 is recorded in EDC, however sample is reported with 01JAN2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:46:37
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 01JAN2021 for Day 5 is recorded in EDC, however sample is reported with 01JAN2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:23:21
User entered '01 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	05 Jan 2021 00:52:48
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	30 Dec 2020 17:43:08

US3682040

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:04:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:58:32
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 00:52:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 00:52:48
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	05 Jan 2021 00:52:48
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 17:43:08
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:58:32
Query 'Per GCL Lab Recon: Saliva: Sample dated 03JAN2021 for Day 7 is recorded in EDC, however sample is reported with 03JAN2020 for Day 7 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:47:03
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 03JAN2021 for Day 7 is recorded in EDC, however sample is reported with 03JAN2020 for Day 7 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:28:28
User entered '03 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	05 Jan 2021 00:52:48
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	30 Dec 2020 17:43:08

US3682040

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:04:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:58:32
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 18:40:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 18:40:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 18:40:11
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 17:43:08
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:58:32
Query 'Per GCL Lab Recon: Saliva: Sample dated 05JAN2021 for Day 9 is recorded in EDC, however sample is reported with 05JAN2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:47:12
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 05JAN2021 for Day 9 is recorded in EDC, however sample is reported with 05JAN2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:29:00
User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 18:40:11
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08



**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:58:32
Query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:11:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 10:10:52
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	11 Jan 2021 19:07:15
User opened query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:18:37
Query 'Data is required. Please complete.' answered with 'scheduled 1/10' (Site from System).	(b) (4), (b) (6)	07 Jan 2021 18:26:28
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 17:43:08
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:58:32
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:07:15
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	30 Dec 2020 17:43:08

US3682040

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:04:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 03:10:00
Query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:22:41
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 22:58:32
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	20 Jan 2021 01:25:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 03:50:14
User opened query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:19:49
Query 'Data is required. Please complete.' answered with 'scheduled 1/17' (Site from System).	(b) (4), (b) (6)	07 Jan 2021 18:26:47
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 17:43:08
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:58:32
User entered '17 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	20 Jan 2021 01:25:47
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	30 Dec 2020 17:43:08

US3682040

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:04:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:43:15
User closed query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:59:30
Query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' answered with 'Data completed' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:49:17
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 19:47:54
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 19:47:54
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 22:58:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 03:50:28
User opened query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:20:13
Query 'Data is required. Please complete.' answered with 'scheduled 1/25' (Site from System).	(b) (4), (b) (6)	07 Jan 2021 18:27:05
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 17:43:08
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08



**US3682040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:43:17
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 19:47:54
User entered '25 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 19:47:54
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 22:58:32
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:43:08

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:17:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 21:56:02

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:17:18
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 21:56:02

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:17:18
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Nov 2020 21:56:02

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:03
User entered 'SICKD1'	System	25 Nov 2020 21:56:02

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:17:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:17:31
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:17:34
User entered '13:32'	(b) (4), (b) (6)	25 Nov 2020 22:28:48



**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User entered '25 Nov 2020 13:32'	System	25 Nov 2020 22:28:48

US3682040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:52:14
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:52:08
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation confirmed.' (Site from CRA).	Jesse Clark (b) (4)	22 Feb 2021 22:33:04
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:18:17
User entered '67' in	(b) (4), (b) (6)	25 Nov 2020 22:28:48
DataPoint set to visible.	System	25 Nov 2020 21:56:02

US3682040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:18:26
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Nov 2020 22:29:46
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	25 Nov 2020 22:29:46
User entered '84' kg reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 22:29:46
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Nov 2020 22:28:48
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 22:28:48
DataPoint set to visible.	System	25 Nov 2020 21:56:02

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:18:29
User entered '98.6' F	(b) (4), (b) (6)	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:18:34
User entered 'Other (Other)'	(b) (4), (b) (6)	25 Nov 2020 22:28:48

US3682040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:18:43
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	25 Nov 2020 22:30:42
User entered 'touchless' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 22:30:42
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	25 Nov 2020 22:28:48
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:18:45
User entered '88'	(b) (4), (b) (6)	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User entered 'bpm'	System	25 Nov 2020 22:28:48



**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:18:48
User entered '16'	(b) (4), (b) (6)	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User entered 'breaths/min'	System	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:18:51
User entered '139'	(b) (4), (b) (6)	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User entered 'mmHg'	System	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:19:01
User entered '96'	(b) (4), (b) (6)	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20
User entered 'mmHg'	System	25 Nov 2020 22:28:48

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:20



**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:19:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 21:58:37

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:19:41
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 21:58:37

US3682040

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 23:04:14

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:33
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:20:45
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession#1F60ET0 ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:13:08
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession#1F60ET0 ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 23:51:01
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 03:36:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 21:56:13

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:33
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:20:45
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 21:56:13

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:50:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 19:03:42

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:50:38
User entered '28 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 19:03:42

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:50:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Dec 2020 19:03:42

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	28 Dec 2020 19:03:42



**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered '28 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered '09:54'	(b) (4), (b) (6)	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User entered '28 Dec 2020 09:54'	System	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered '67' in	(b) (4), (b) (6)	28 Dec 2020 21:47:26
DataPoint set to visible.	System	28 Dec 2020 19:03:42

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered '196.8' lb	(b) (4), (b) (6)	28 Dec 2020 21:47:26
DataPoint set to visible.	System	28 Dec 2020 19:03:42

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered '98.6' F	(b) (4), (b) (6)	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Dec 2020 21:47:26



**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered '61'	(b) (4), (b) (6)	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered '20'	(b) (4), (b) (6)	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User entered '185'	(b) (4), (b) (6)	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Dec 2020 21:47:26

US3682040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:05
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 04:41:50
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 04:36:19
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	28 Dec 2020 21:47:38
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	28 Dec 2020 21:47:33
User opened query 'Diastolic Blood Pressure reportedSystem is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		28 Dec 2020 21:47:26
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		28 Dec 2020 21:47:26
User entered '118'	(b) (4), (b) (6)	28 Dec 2020 21:47:26



**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Dec 2020 21:47:26

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 21:48:01

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:14
User entered '28 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 21:48:01

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 23:04:14**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 22:51:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 19:03:54

**US3682040**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 22:51:36
User entered '28 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 19:03:54

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	25 Jan 2021 19:46:54

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	25 Jan 2021 19:46:54

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:37:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:46:54



**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:37:51
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:46:54

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:37:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Jan 2021 19:46:54

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'SICKD28'	System	25 Jan 2021 19:46:54

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 20:46:03

US3682040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:29
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:34
User entered '09:16'	(b) (4), (b) (6)	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered '25 Jan 2021 09:16'	System	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:37
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 20:46:03
DataPoint set to visible.	System	25 Jan 2021 19:46:54



**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 20:46:03
DataPoint set to visible.	System	25 Jan 2021 19:46:54

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:41
User entered '98.1' F	(b) (4), (b) (6)	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:44
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:46
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:49
User entered '69'	(b) (4), (b) (6)	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'bpm'	System	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:52
User entered '20'	(b) (4), (b) (6)	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'breaths/min'	System	25 Jan 2021 20:46:03



**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:54
User entered '148'	(b) (4), (b) (6)	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'mmHg'	System	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:40:56
User entered '98'	(b) (4), (b) (6)	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'mmHg'	System	25 Jan 2021 20:46:03

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:41:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 20:46:35

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:41:29
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 20:46:35



**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 23:04:14**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:42:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:47:07

**US3682040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:42:19
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:47:07

**US3682040**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:07
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	04 Feb 2021 21:18:56

**US3682040**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:07
User entered '4 Feb 2021'	Jesse Clark (b) (4) (b) (4)	04 Feb 2021 21:18:56

**US3682040**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:07
User entered 'Clinic (Clinic)'	Jesse Clark (b) (4) (b) (4)	04 Feb 2021 21:18:56

**US3682040**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 21:18:56

**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:18
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:13:52



**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
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 18:13:52

**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:18
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:18
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:18
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:18
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '1'	System	04 Feb 2021 22:05:11



**US3682040**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'I'	System	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered empty.	System	04 Feb 2021 22:06:02
DataPoint set to visible.	System	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered empty.	System	04 Feb 2021 22:06:02
DataPoint set to visible.	System	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Feb 2021 22:06:02



**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:47
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:49
User entered '13:05'	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '4 Feb 2021 13:05'	System	04 Feb 2021 22:06:02

US3682040

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:04:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Feb 2021 22:06:11
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 22:06:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Feb 2021 22:06:02
User entered '98.8' (non-conformant).	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:57
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:45:00
User entered '75'	(b) (4), (b) (6)	04 Feb 2021 22:06:02



**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'bpm'	System	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:45:03
User entered '16'	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'breaths/min'	System	04 Feb 2021 22:06:02

US3682040

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:04:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:04:58
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:04:55
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation edited for clarity.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 22:34:08
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:45:43
User entered '133'	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'mmHg'	System	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:45:12
User entered '79'	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'mmHg'	System	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 22:06:02



**US3682040**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:44:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 22:06:02

**US3682040**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered empty.	System	04 Feb 2021 22:06:02
DataPoint set to visible.	System	04 Feb 2021 22:05:11

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:05:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:05:20
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:05:29
User entered '14:25'	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '4 Feb 2021 14:25'	System	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:05:37
User entered '97.8' F	(b) (4), (b) (6)	04 Feb 2021 22:46:33



**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:05:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:05:47
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:05:56
User entered '54'	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'bpm'	System	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:06:05
User entered '16'	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'breaths/min'	System	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:07:24
User entered '115'	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'mmHg'	System	04 Feb 2021 22:46:33



**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:07:25
User entered '74'	(b) (4), (b) (6)	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'mmHg'	System	04 Feb 2021 22:46:33

**US3682040**

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

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 22:06:22

**US3682040**

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

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:45:56
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 22:06:22

**US3682040**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:36:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 22:06:38

**US3682040**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:36:53
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 22:06:38

US3682040

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

Form: Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:36:54
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 22:06:38

US3682040

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

Form: Exposure

Generated On: 11 Aug 2021 23:04:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User closed query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 20:37:01
Query 'This is not in source document. Please verify and update accordingly.' answered with 'Source documentation confirmed.' (Site from CRA).	Jesse Clark (b) (4)	22 Feb 2021 22:31:04
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:47:23
User entered 'mRNA-1273'	System	04 Feb 2021 22:06:38
DataPoint set to visible.	System	04 Feb 2021 22:05:11



US3682040

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

Form: Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:37:22
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 22:06:38

**US3682040**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:12:46
User entered '13:50'	(b) (4), (b) (6)	04 Feb 2021 22:06:38

**US3682040**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '4 Feb 2021 13:50'	System	04 Feb 2021 22:06:38

**US3682040**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:37:26
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	04 Feb 2021 22:06:38

**US3682040**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:12:42
User entered 'ONCE'	System	04 Feb 2021 22:06:38

**US3682040**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 22:06:38

US3682040

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:04:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:47:42
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 23:57:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 23:57:35
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	04 Feb 2021 23:57:35
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 22:56:08
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 22:56:08

**US3682040**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:47:42
User entered '04 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	04 Feb 2021 23:57:35
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 22:56:08



**US3682040**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:47:42
User entered '13:35' reason for change: New Information	(b) (4), (b) (6)	04 Feb 2021 23:57:35
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 22:56:08

**US3682040**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '04 Feb 2021 13:35'	System	04 Feb 2021 23:57:35
User entered empty.	System	04 Feb 2021 22:56:08

US3682040

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:04:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:48:00
DataPoint Un-verified.	(b) (4), (b) (6)	20 Feb 2021 00:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:47:55
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	04 Feb 2021 23:57:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Jan 2021 19:02:42
Query 'Data is required. Please complete.' answered with 'Data entry error' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 19:46:31
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 19:46:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:46:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:46:00

**US3682040**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:04:14**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:47:55
User entered '04 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	04 Feb 2021 23:57:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:46:24
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:46:00

**US3682040**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:47:55
User entered '13:37' reason for change: New Information	(b) (4), (b) (6)	04 Feb 2021 23:57:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:46:24
User entered '09:35'	(b) (4), (b) (6)	25 Jan 2021 19:46:00

**US3682040**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '04 Feb 2021 13:37'	System	04 Feb 2021 23:57:57
User entered empty.	System	25 Jan 2021 19:46:24
User entered '25 Jan 2021 09:35'	System	25 Jan 2021 19:46:00

**US3682040**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:48:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 22:06:45

**US3682040**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'I'	System	04 Feb 2021 22:06:45



**US3682040**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:54:36
Query 'This is not in source document. Please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 21:54:34
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:28:39
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	11 Feb 2021 19:06:39

**US3682040**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:54:36
User entered '11 Feb 2021'	Jesse Clark (b) (4) (b) (4)	11 Feb 2021 19:06:39

**US3682040**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:54:36
User entered 'Contact Made (CONTACT MADE)'	Jesse Clark (b) (4) (b) (4)	11 Feb 2021 19:06:39

**US3682040**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:54:36
User entered empty.	Jesse Clark (b) (4) (b) (4)	11 Feb 2021 19:06:39

**US3682040**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:10:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:54:41
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	11 Feb 2021 21:03:14

**US3682040**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'I'	System	11 Feb 2021 21:03:14

**US3682040**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '1'	System	11 Feb 2021 21:03:14
DataPoint set to visible.	System	11 Feb 2021 21:03:14

**US3682040**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:31:32



**US3682040**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:31:32

**US3682040**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:31:32

**US3682040**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'OLD29'	System	01 Mar 2021 23:31:32

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '14:15'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '1 Mar 2021 14:15'	System	01 Mar 2021 23:32:20



**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '80'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'bpm'	System	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'breaths/min'	System	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '134'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20



**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'mmHg'	System	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '88'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'mmHg'	System	01 Mar 2021 23:32:20

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '15:07'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '1 Mar 2021 15:07'	System	01 Mar 2021 23:32:54



**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '72'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'bpm'	System	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'breaths/min'	System	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '140'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54



**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'mmHg'	System	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '94'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'mmHg'	System	01 Mar 2021 23:32:54

**US3682040**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:02

**US3682040**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:02

**US3682040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:43

**US3682040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:43

US3682040

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:43



**US3682040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'mRNA-1273'	System	01 Mar 2021 23:33:43
DataPoint set to visible.	System	11 Feb 2021 21:03:14

**US3682040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:43

**US3682040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '14:32'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:43

**US3682040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered '01 Mar 2021 14:32'	System	01 Mar 2021 23:33:43

**US3682040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:43

**US3682040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'ONCE'	System	01 Mar 2021 23:33:43

**US3682040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:04:14**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 23:33:43

**US3682040**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:49



**US3682040**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'I'	System	01 Mar 2021 23:33:49

**US3682040**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Yes (Y)'	Jesse Clark (b) (4)	08 Mar 2021 21:39:51

**US3682040**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered '8 Mar 2021'	Jesse Clark (b) (4)	08 Mar 2021 21:39:51

**US3682040**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Contact Made (CONTACT MADE)'	Jesse Clark (b) (4)	08 Mar 2021 21:39:51

**US3682040**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:04:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered empty.	Jesse Clark (b) (4)	08 Mar 2021 21:39:51

**US3682040**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:29:11
User entered 'Yes (Y)'	Jesse Clark (b) (4)	08 Mar 2021 21:40:00

**US3682040**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:04:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:35
User entered 'I'	System	08 Mar 2021 21:40:00

**US3682040**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Yes (Y)'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:05
	(b) (4)	



**US3682040**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '29 Mar 2021'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:05
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Clinic (Clinic)'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:05
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:04:14**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 21:36:05

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Yes (Y)'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:37
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '29 Mar 2021'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:37
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '13:58'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:37
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 13:58'	System	29 Mar 2021 21:36:37

US3682040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	29 Mar 2021 21:36:50
User entered '97.7' F reason for change: New Information	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Mar 2021 21:36:37
User entered '97.7' (non-conformant).	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:37



**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Oral (Oral)'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:37
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered empty.	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:37
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '77'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:37
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 21:36:37

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '16'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:37
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 21:36:37

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '176'	Schuyler Thomas (b) (4)	29 Mar 2021 21:36:37
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 21:36:37



US3682040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:04:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 06:51:16
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Schuyler Thomas (b) (4) (b) (4)	29 Mar 2021 21:36:48
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		29 Mar 2021 21:36:37
User entered '108'	Schuyler Thomas (b) (4) (b) (4)	29 Mar 2021 21:36:37

**US3682040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:04:14**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 21:36:37

**US3682040**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Yes (Y)'	Schuyler Thomas (b) (4)	29 Mar 2021 21:37:21
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:04:14**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '29 Mar 2021'	Schuyler Thomas (b) (4)	29 Mar 2021 21:37:21
	(b) (4)	

**US3682040**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:00:06

**US3682040**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:00:06

**US3682040**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered '14:22'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:00:06

**US3682040**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 14:22'	System	30 Mar 2021 00:00:06



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 23:04:14**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:53:57
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:50:25
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 23:40:43
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:40:37
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:21:53

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10

US3682040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:04:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:06
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 23:24:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 23:24:48
Data point term sent to Coder	System	15 Sep 2020 23:23:56
User entered 'Headache'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:08
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:10
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:37:11
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:14
User entered '15 Sep 2020'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:28
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User entered empty.	System	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:19
User entered 'No (N)' reason for change: Per Query Resolution	Susan Reed (b) (4) (b) (4)	13 Oct 2020 22:57:37
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

US3682040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:04:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:30
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Oct 2020 22:57:51
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	13 Oct 2020 22:57:51
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Oct 2020 22:57:37
User entered '15 Sep 2020' reason for change: New Information	Susan Reed (b) (4)	13 Oct 2020 22:57:37
User entered empty.	Susan Reed (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:38
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User entered empty.	System	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:43
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:45
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:47
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

US3682040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:04:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:52
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:55
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:57
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:00
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:02
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:04
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:06
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:08
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:11
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:13
User entered 'None (NONE)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:23
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:31
User entered 'l'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:54:35
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

US3682040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:04:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:40:09
User closed query 'This is stated as "recovering" in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:40:07
Query 'This is stated as "recovering" in source document. Please verify and update accordingly.' answered with 'Source documentation corrected.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:50:30
User opened query 'This is stated as "recovering" in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:59:37
Query 'This stated as "recovering" in source document. Please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:59:23
User opened query 'This stated as "recovering" in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:55:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	13 Oct 2020 22:57:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:40:13
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:40:16
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User entered '0'	System	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10
User entered '0'	System	15 Sep 2020 23:23:37

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:10

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:55:53
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Varicella zoster virus infection, LLT: Varicella zoster - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:11
Data point term sent to Coder	System	16 Oct 2020 20:14:18
Coding entries removed.	Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:13:33
User entered 'Exacerbation of VARICELLA ZOSTER' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:13:33
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Varicella zoster virus infection, LLT: Varicella zoster - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:39:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:39:35
Data point term sent to Coder	System	29 Sep 2020 16:38:59
User entered 'Varicella zoster'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:55:56
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:55:58
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:55:59
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:56:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Oct 2020 20:09:15
User entered '01 Sep 2020' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:09:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Oct 2020 20:08:23
User entered 'un Aug 2020' (non-conformant).	Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:08:23
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	29 Sep 2020 16:39:41
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify.' (Site from System).	System	29 Sep 2020 16:39:41
User entered '1 Sep 2020' reason for change: Data Entry Error	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:39:41
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	29 Sep 2020 16:38:27
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify.' (Site from System).	System	29 Sep 2020 16:38:27
User entered '30 Aug 2020'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

US3682040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:40:56
User closed query 'start time in source document is 2300. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:40:54
Query 'start time in source document is 2300. Please verify and update accordingly.' answered with 'Entry corrected.' (Site from CRA).	Jesse Clark (b) (4)	22 Feb 2021 21:51:36
User entered '23:00' reason for change: Data Entry Error	Jesse Clark (b) (4)	22 Feb 2021 21:51:26
User opened query 'start time in source document is 2300. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:57:04
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:14:30
User entered '10:55' reason for change: Data Entry Error	Susan Reed (b) (4)	16 Oct 2020 20:14:30
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:09:15
User entered empty; reason for change Data Entry Error	Susan Reed (b) (4)	16 Oct 2020 20:08:23
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 16:40:33
User entered '23:00' reason for change: Data Entry Error	Jesse Clark (b) (4)	29 Sep 2020 16:40:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 16:40:20
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:40:20
User entered '24:00' (non-conformant).	Jesse Clark (b) (4)	29 Sep 2020 16:40:20
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:39:41
User entered empty.	Jesse Clark (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User entered '01 Sep 2020 23:00'	System	22 Feb 2021 21:51:26
User entered '01 Sep 2020 10:55'	System	16 Oct 2020 20:14:30
User entered empty.	System	16 Oct 2020 20:08:23
User entered '1 Sep 2020 23:00'	System	29 Sep 2020 16:40:33
User entered '1 Sep 2020 24:00' (non-conformant).	System	29 Sep 2020 16:40:20
User entered empty.	System	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:20
User entered 'No (N)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	06 Oct 2020 22:33:59
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:22
User entered '03 Oct 2020' reason for change: New Information	Susan Reed (b) (4) (b) (4)	06 Oct 2020 22:33:59
User entered empty.	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 12:44:54
User closed query 'Per CDM: End time is present for an AE that did not stop within 24 hours after dosing. Please consider to remove the End time or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:44:51
Query 'Data is required. Please provide.' answered with 'data removed per query' (Site from System).	Susan Reed (b) (4)	23 Oct 2020 18:21:51
Query 'Per CDM: End time is present for an AE that did not stop within 24 hours after dosing. Please consider to remove the End time or else clarify. Thank you' answered with 'data removed' (Site from DM).	Susan Reed (b) (4)	23 Oct 2020 18:21:40
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 18:21:26
User entered empty; reason for change New Information	Susan Reed (b) (4)	23 Oct 2020 18:21:26
User opened query 'Per CDM: End time is present for an AE that did not stop within 24 hours after dosing. Please consider to remove the End time or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:03:56
User closed query 'Per CDM: End time is present for an AE that did not stop within 24 hours after dosing. Please consider to remove the End time or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:09:33
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:15:29
User entered '23:59' reason for change: New Information	Susan Reed (b) (4)	16 Oct 2020 20:15:29
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:14:44
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Oct 2020 20:14:44
User entered empty; reason for change New Information	Susan Reed (b) (4)	16 Oct 2020 20:14:44

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Oct 2020 20:14:30
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:14:30
User entered 'un:un' (non-conformant).	Susan Reed (b) (4)	16 Oct 2020 20:14:30
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:09:15
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:08:23
Query 'Per CDM: End time is present for an AE that did not stop within 24 hours after dosing. Please consider to remove the End time or else clarify. Thank you' answered with 'form updated' (Site from DM).	Susan Reed (b) (4)	16 Oct 2020 20:03:10
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:03:00
User entered empty; reason for change New Information	Susan Reed (b) (4)	16 Oct 2020 20:03:00
User opened query 'Per CDM: End time is present for an AE that did not stop within 24 hours after dosing. Please consider to remove the End time or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:44:06
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 22:34:51
User entered '08:00' reason for change: New Information	Susan Reed (b) (4)	06 Oct 2020 22:34:51
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 22:33:59
User entered empty.	Jesse Clark (b) (4)	29 Sep 2020 16:38:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User entered empty.	System	23 Oct 2020 18:21:26
User entered '03 Oct 2020 23:59'	System	16 Oct 2020 20:15:29
User entered empty.	System	16 Oct 2020 20:14:44
User entered '03 Oct 2020 UN:UN' (non-conformant).	System	16 Oct 2020 20:14:30
User entered empty.	System	16 Oct 2020 20:03:00
User entered '03 Oct 2020 08:00'	System	06 Oct 2020 22:34:51
User entered empty.	System	29 Sep 2020 16:38:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:36
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:47:03
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' answered with 'Updated to Grade 2' (Site from DM).	Jesse Clark (b) (4) (b) (4)	18 Nov 2020 18:33:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Per Query Resolution	Jesse Clark (b) (4) (b) (4)	18 Nov 2020 18:33:18
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:46:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:39
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:41
User entered '0'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:44
User entered '0'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:46
User entered '0'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:48
User entered empty.	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:50
User entered empty.	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:52
User entered empty.	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:53
User entered empty.	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:56
User entered '0'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:58
User entered '0'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:01
User entered '0'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:05
User entered 'Related (RELATED)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:13
User entered 'Not Related (NOT RELATED)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27



US3682040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:15
User closed query 'Per CDM: Please complete the Dosing Discontinuation page. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 14:32:14
Query 'Per CDM: Please complete the Dosing Discontinuation page. Thank you.' answered with 'dosing discontinuation crf completed' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Oct 2020 19:26:16
User opened query 'Per CDM: Please complete the Dosing Discontinuation page. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:55:22
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:21
User entered 'l'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:25
User entered '0'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:40
User entered '0'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

US3682040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:41:14
User closed query 'This is stated as "recovering" in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:41:12
Query 'This is stated as "recovering" in source document. Please verify and update accordingly.' answered with 'Source document corrected.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:51:58
User opened query 'This is stated as "recovering" in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:59:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	06 Oct 2020 22:33:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:41:18
User entered empty.	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

US3682040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:04:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:02
User entered 'PARTICIPANT REPORTS ONSET OF VESICULAR RASH CONSISTENT WITH VARICELLA ZOSTER IN V1 DISTRIBUTION OF TRIGEMINAL NERVE. Participant believes symptoms started prior to first injection, but not noted on history or physical exam at that time. NO EYE PAIN, NO VISUAL CHANGES. ON PHYSICAL EXAM, ALL LESIONS CRUSTING WITH NO VISIBLE VESICLES. REFERRED TO PMD FOR EVALUATION AND ACYCLOVIR TREATMENT. DUE TO CONCERN FOR POSSIBLE REACTIVATION FROM IMMUNE ACTIVATION WITH SECOND INJECTION, STUDY PRODUCT DISCONTINUED.' reason for change: Data Entry Error	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:39:41
User entered 'Participant reports onset of vesicular rash consistent with varicella zoster in V1 distribution of trigeminal nerve. No eye pain, no visual changes. On physical exam, all lesions crusting with no visible vesicles. Referred to PMD for evaluation and acyclovir treatment. Due to concern for possible reactivation from immune activation with second injection, study product discontinued.'	Jesse Clark (b) (4) (b) (4)	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User entered '0'	System	29 Sep 2020 16:38:27



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15
User entered '0'	System	29 Sep 2020 16:38:27

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:15

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:17
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:35
User entered 'USA-US081-2021-mRNA-1273-P301000001'	System	07 Jan 2021 20:50:30
User entered 'New'	(b) (4), (b) (6)	07 Jan 2021 20:50:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:04:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Jan 2021 18:35:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Jan 2021 18:35:52
Data point term sent to Coder	System	07 Jan 2021 18:34:48
User entered 'Symptomatic COVID 19'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:21
User entered 'No (N)'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:23
User entered 'No (N)'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:31
User entered '21 Dec 2020'	(b) (4), (b) (6)	07 Jan 2021 18:34:36



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:37
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:34
User entered 'No (N)'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:06:58
User entered '1 Jan 2021'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:03
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:17
User entered 'No (N)'	(b) (4), (b) (6)	07 Jan 2021 18:34:36



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:19
User entered '0'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:21
User entered '0'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:23
User entered '0'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:25
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:27
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:28
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:30
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:32
User entered '0'	(b) (4), (b) (6)	07 Jan 2021 18:34:36



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:34
User entered '0'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:36
User entered '0'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:04:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:38
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 18:34:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 18:34:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 18:34:44
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 18:34:36
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:04:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:40
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 18:34:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 18:34:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 18:34:44
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 18:34:36
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:09:15
DataPoint Un-verified.	(b) (4), (b) (6)	20 Feb 2021 01:09:08
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 01:07:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:45
User entered '0'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:04:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:07:47
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 18:47:11
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Conmed eCRF updated' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:15:22
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:45:15
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:08:13
User entered '0'	(b) (4), (b) (6)	07 Jan 2021 18:34:36



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:08:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:08:28
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:11:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:08:38
User closed query 'PV Query: Please provide a completed COVID-19 severity assessment form.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 00:29:23
Query 'PV Query: Please provide a completed COVID-19 severity assessment form.' answered with 'completed' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 21:39:43
User opened query 'PV Query: Please provide a completed COVID-19 severity assessment form.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 12:38:20
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Jan 2021 18:34:36

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Jan 2021 18:34:36

US3682040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:04:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Mar 2021 21:28:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 21:28:30
Data point term sent to Coder	System	25 Mar 2021 21:28:04
User entered 'COVID-like illness'	Mitchell Stern (b) (4) (b) (4)	25 Mar 2021 21:27:39

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '22 Nov 2020'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 21:27:39

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '26 Nov 2020'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 21:27:39



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	



**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	



US3682040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:04:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:30:09
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'conmed updated accordingly' (Site from DM).	Mitchell Stern (b) (4)	05 Apr 2021 22:10:01
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:01:54
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'I'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mitchell Stern (b) (4)	25 Mar 2021 21:27:39

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	25 Mar 2021 21:27:39
	(b) (4)	

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 21:27:39

**US3682040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 21:27:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 23:04:14**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:53:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:09:27
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:42:59



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:04:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:09:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NIFEDIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:44:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:44:57
Data point term sent to Coder	System	01 Sep 2020 17:43:50
User entered 'Nifedipine'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:09:48
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:09:50
User entered 'Hypertension'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:09:53
User entered '30'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:09:55
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:09:57
User entered empty.	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:04:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:44:04
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:44:01
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation confirmed ("QD" = "Once Daily").' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:53:05
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 01:10:28
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:31
User entered empty.	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:34
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:37
User entered empty.	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:39
User entered 'un UNK 2018'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:41
User entered '0'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:46
User entered 'No (N)' reason for change: Data Entry Error	Oladunni Adeyiga (b) (4)	25 Jan 2021 19:53:17
User entered 'Yes (Y)'	Jesse Clark (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:48
User entered '15 Jan 2021' reason for change: Data Entry Error	Oladunni Adeyiga (b) (4)	25 Jan 2021 19:53:17
User entered empty.	Jesse Clark (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:50
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User entered '1'	System	01 Sep 2020 17:43:34



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User entered '1'	System	01 Sep 2020 17:43:34

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:27
User entered '804 (804)'	System	01 Sep 2020 17:43:34

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:27:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:27:54
Data point term sent to Coder	System	11 Feb 2021 18:13:30
Data point term sent to Coder	System	11 Feb 2021 18:12:29
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 18:12:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 23:25:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 23:25:49
Data point term sent to Coder	System	15 Sep 2020 23:24:59
User entered 'Tylenol'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:10:57
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:11:00
User entered 'HEADACHE' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 18:12:32
User entered 'symptomatic COVID-19; HEADACHE' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 18:12:17
User entered 'Headache'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:11:05
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 17:04:01
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' answered with 'data updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	12 Oct 2020 19:47:20
User entered '1000' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	12 Oct 2020 19:43:47
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:08:07
User entered '2'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:11:07
User entered 'mg (mg)' reason for change: Data Entry Error	Susan Reed (b) (4)	12 Oct 2020 19:43:47
User entered 'tablet (TABLET)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:11:09
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55



US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:45:59
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:45:54
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation confirmed ("PRN" = "As Needed").' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:53:29
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 01:11:33
User entered 'as needed (PRN)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:46:06
DataPoint Un-verified.	(b) (4), (b) (6)	20 Feb 2021 01:11:39
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 01:11:36
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:11:42
User entered 'Oral (ORAL)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:04:14**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:11:44
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:11:46
User entered '15 Sep 2020'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:11:48
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:11:59
User entered 'No (N)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	13 Oct 2020 22:55:09
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:12:01
User entered '15 Sep 2020' reason for change: New Information	Susan Reed (b) (4) (b) (4)	13 Oct 2020 22:55:09
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55



US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:04:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:12:04
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Headache in eDiary and AE indicates this condition is an Unsolicited event. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 09:22:39
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Headache in eDiary and AE indicates this condition is an Unsolicited event. Review if this should be updated to No.' answered with 'ae crf states "was this a solicited adverse reaction" which is no, this was a solicited ae event, thus the yes.' (Site from DM).	Susan Reed (b) (4) (b) (4)	12 Oct 2020 19:50:20
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Headache in eDiary and AE indicates this condition is an Unsolicited event. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:07:51
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	15 Sep 2020 23:24:55

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User entered empty.	System	15 Sep 2020 23:24:55

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User entered empty.	System	15 Sep 2020 23:24:55

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:31
User entered empty.	System	15 Sep 2020 23:24:55

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:04:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Feb 2021 01:12:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 20:10:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 20:10:52
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 20:10:02
Coding entries removed.	Susan Reed (b) (4)	15 Dec 2020 20:09:39
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 22:02:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 22:02:40
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 17:50:22
User entered 'GABAPENTIN'	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:12:16
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:12:20
User entered 'Lower Back Pain' reason for change:	Susan Reed (b) (4)	15 Dec 2020 20:09:39
Data Entry Error	(b) (4)	
User entered 'LBP'	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:12:24
User entered '300'	(b) (4), (b) (6)	23 Sep 2020 17:49:30



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:12:26
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:12:28
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:49:30

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:04:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4)	01 Mar 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:46:27
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation confirmed ("PRN" = "As Needed").' (Site from CRA).	Jesse Clark (b) (4)	22 Feb 2021 21:53:42
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4)	20 Feb 2021 01:12:54
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:46:32
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:12:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:03
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:05
User entered '1 Sep 2015'	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:07
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 17:49:30



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:11
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:13
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:49:30

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:49:30

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:04:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Feb 2021 01:13:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 20:10:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 20:10:52
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	15 Dec 2020 20:10:02
	Susan Reed (b) (4)	15 Dec 2020 20:09:56
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:51:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:51:43
	(b) (4)	
Data point term sent to Coder User entered 'ROBAXIN'	System	23 Sep 2020 17:50:23
	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:26
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:50:18



US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:04:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:24
User entered 'Lower Back Pain' reason for change:	Susan Reed (b) (4)	15 Dec 2020 20:09:56
Data Entry Error	(b) (4)	
User entered 'LBP'	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:28
User entered '750'	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:30
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:32
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:50:18

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:04:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4)	01 Mar 2021 21:47:04
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:46:50
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation confirmed ("PRN" = "As Needed").' (Site from CRA).	Jesse Clark (b) (4)	22 Feb 2021 21:53:55
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4)	20 Feb 2021 01:13:53
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:47:06
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:13:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:00
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:50:18



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:03
User entered '1 Sep 2015'	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:05
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:08
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:10
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:50:18

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:50:18



US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:04:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 22:12:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	05 Apr 2021 22:11:46
	Mitchell Stern (b) (4)	05 Apr 2021 22:10:46
User signature succeeded.	(b) (4)	
	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Feb 2021 01:14:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:51:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:51:09
	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 23:50:20
User entered 'Acetaminophen'	Mitchell Stern (b) (4)	25 Nov 2020 23:50:06
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:17
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:04:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 17:59:29
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 11:51:47
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:51:31
DataPoint Un-verified.	Mitchell Stern (b) (4)	05 Apr 2021 22:10:46
Signature has been broken.	(b) (4) Mitchell Stern (b) (4)	05 Apr 2021 22:10:46
User entered 'COVID-like Illness (BODY ACHES, HEADACHE)' reason for change: Per Query Resolution	(b) (4) Mitchell Stern (b) (4)	05 Apr 2021 22:10:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:27
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 03:59:35
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'subject assessed for COVID-19 symptoms and scheduled for an illness visit ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 23:44:49

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:39:34
User entered 'body aches, headache'	Mitchell Stern (b) (4)	25 Nov 2020 23:50:06

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:29
User entered '1000'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:37
User entered 'mg (mg)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:04:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:38
User entered empty.	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:04:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:47:35
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:47:28
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation confirmed ("PRN" = "As Needed").' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:54:04
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 01:14:46
User entered 'as needed (PRN)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06



US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:04:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:47:36
User entered empty.	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:50
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:53
User entered empty.	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:55
User entered '22 Nov 2020'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:57
User entered '0'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:14:58
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	28 Dec 2020 23:05:21
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:04:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:01
User entered '27 Nov 2020' reason for change: Data Entry Error	Mitchell Stern (b) (4)	28 Dec 2020 23:06:38
User entered '22 Nov 2020' reason for change: Data Entry Error	Mitchell Stern (b) (4)	28 Dec 2020 23:05:21
User entered empty.	Mitchell Stern (b) (4)	25 Nov 2020 23:50:06

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:04:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 23:44:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 23:43:47
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	25 Nov 2020 23:50:06



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User entered empty.	System	25 Nov 2020 23:50:06

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User entered empty.	System	25 Nov 2020 23:50:06

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:35
User entered empty.	System	25 Nov 2020 23:50:06

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:04:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:13:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:13:55
Data point term sent to Coder	System	11 Feb 2021 18:13:31
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 18:13:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 23:49:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 23:49:32
Data point term sent to Coder	System	29 Dec 2020 23:48:31
User entered 'Acetaminophen'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:14
User entered 'No (N)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:04:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:21
User entered 'Symptomatic COVID19; HEADACHE' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 18:13:09
User entered 'headache'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:23
User entered '1000'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:24
User entered 'mg (mg)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:28
User entered empty.	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:04:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:47:56
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:47:53
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation confirmed ("PRN" = "As Needed").' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:54:18
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 01:15:34
User entered 'as needed (PRN)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:04:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:47:58
User entered empty.	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:40
User entered 'Oral (ORAL)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:45
User entered empty.	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:54
User entered '28 Dec 2020'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:56
User entered '0'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:15:58
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Feb 2021 18:15:04
User entered 'Yes (Y)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:00
User entered '31 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 18:15:04
User entered empty.	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:04:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User closed query 'Per CDM, DM CLR RQ: Response noted. Please review if this field should be updated to No as the indication does not indicate a solicited event per protocol. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 10:06:00
Query 'Per CDM, DM CLR RQ: Response noted. Please review if this field should be updated to No as the indication does not indicate a solicited event per protocol. ' answered with 'reviewed and updated' (Site from DM).	Jesse Clark (b) (4)	08 Apr 2021 17:59:29
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 17:22:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 17:22:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:22:33
User opened query 'Per CDM, DM CLR RQ: Response noted. Please review if this field should be updated to No as the indication does not indicate a solicited event per protocol. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:52:03
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there are no corresponding records in eDiary. Please note that this CM was given after 7-days reporting period of SAR and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:52:03

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:04:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there are no corresponding records in eDiary. Please note that this CM was given after 7-days reporting period of SAR and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' answered with 'subject was positive for COVID-19. Symptomatic Covid 19 infection 12/21-01/01/21' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 20:47:37
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there are no corresponding records in eDiary. Please note that this CM was given after 7-days reporting period of SAR and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.	(b) (4), (b) (6)	06 Apr 2021 11:53:08
' (Site from DM).		
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:02
User entered 'Yes (Y)'	Timothy Hall (b) (4) (b) (4)	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User entered empty.	System	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User entered empty.	System	29 Dec 2020 23:47:39

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:19:39
User entered empty.	System	29 Dec 2020 23:47:39

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:04:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:56:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:56:59
Data point term sent to Coder	System	25 Jan 2021 19:55:27
User entered 'losartan'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:10
User entered 'No (N)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27



US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:04:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:43:08
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'Per subject report condition not worsened. PMD treatment plan was to start on Losartan and hydrochlorothiazide combination for hypertension. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:30:07
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 05:41:02
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 01:16:13
User entered 'hypertension'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:15
User entered '100'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:17
User entered 'mg (mg)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:19
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:04:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4)	01 Mar 2021 21:48:19
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:48:17
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation confirmed ("QD" = "Once Daily").' (Site from CRA).	Jesse Clark (b) (4)	22 Feb 2021 21:54:31
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Feb 2021 01:16:28
	Oladunni Adeyiga (b) (4)	25 Jan 2021 19:54:27
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:48:21
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:33
User entered 'Oral (ORAL)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:36
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:40
User entered '15 Jan 2021'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:43
User entered '0'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:04:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
	(b) (4)	
DataPoint Un-verified.	Jesse Clark (b) (4)	27 Apr 2021 20:40:39
	(b) (4)	
Signature has been broken.	Jesse Clark (b) (4)	27 Apr 2021 20:40:39
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Jesse Clark (b) (4)	27 Apr 2021 20:40:39
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 01:16:47
User entered 'Yes (Y)'	Oladunni Adeyiga (b) (4)	25 Jan 2021 19:54:27
	(b) (4)	

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:04:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
	(b) (4)	
DataPoint Un-verified.	Jesse Clark (b) (4)	27 Apr 2021 20:40:39
	(b) (4)	
Signature has been broken.	Jesse Clark (b) (4)	27 Apr 2021 20:40:39
	(b) (4)	
User entered '19 Apr 2021' reason for change: New Information	Jesse Clark (b) (4)	27 Apr 2021 20:40:39
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 01:16:49
User entered empty.	Oladunni Adeyiga (b) (4)	25 Jan 2021 19:54:27
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:51
User entered 'No (N)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:54:27

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 19:54:27



US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:04:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:46:20
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'per subject report condition not worsened. PMD treatment plan was to start of losartan and HYDROCHLOROTHIAZIDE to treat hypertension. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:28:58
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 05:41:35
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 01:16:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:58:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:58:01
Data point term sent to Coder	System	25 Jan 2021 19:56:28
User entered 'hydrochlorothiazide'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:16:58
User entered 'No (N)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:01
User entered 'hypertension'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:03
User entered '25'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:05
User entered 'mg (mg)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:09
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:04:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4)	01 Mar 2021 21:48:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:48:38
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Source documentation confirmed ("QD" = "Once Daily").' (Site from CRA).	Jesse Clark (b) (4)	22 Feb 2021 21:54:48
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Feb 2021 01:17:16
	Oladunni Adeyiga (b) (4)	25 Jan 2021 19:55:28
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:48:42
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:22
User entered 'Oral (ORAL)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:24
User entered empty.	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:26
User entered '15 Jan 2021'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:28
User entered '0'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:04:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
	(b) (4)	
DataPoint Un-verified.	Jesse Clark (b) (4)	27 Apr 2021 20:41:04
	(b) (4)	
Signature has been broken.	Jesse Clark (b) (4)	27 Apr 2021 20:41:04
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Jesse Clark (b) (4)	27 Apr 2021 20:41:04
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 01:17:30
User entered 'Yes (Y)'	Oladunni Adeyiga (b) (4)	25 Jan 2021 19:55:28
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
	(b) (4)	
DataPoint Un-verified.	Jesse Clark (b) (4)	27 Apr 2021 20:41:04
	(b) (4)	
Signature has been broken.	Jesse Clark (b) (4)	27 Apr 2021 20:41:04
	(b) (4)	
User entered '19 Apr 2021' reason for change: New Information	Jesse Clark (b) (4)	27 Apr 2021 20:41:04
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 01:17:33
User entered empty.	Oladunni Adeyiga (b) (4)	25 Jan 2021 19:55:28
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:35
User entered 'No (N)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:55:28



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:55:28

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 19:55:28

US3682040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:04:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NIFEDIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Apr 2021 21:45:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 21:45:20
Data point term sent to Coder User entered 'Nifedipine'	System Jesse Clark (b) (4) (b) (4)	27 Apr 2021 20:55:22 27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered 'No (N)'	Jesse Clark (b) (4)	27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered 'Hypertension'	Jesse Clark (b) (4)	27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered '30'	Jesse Clark (b) (4)	27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered 'mg (mg)'	(b) (4) Jesse Clark (b) (4) (b) (4)	27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	27 Apr 2021 20:54:41
	(b) (4)	



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered 'once daily (QD)'	(b) (4)	
	Jesse Clark (b) (4)	27 Apr 2021 20:54:41
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	27 Apr 2021 20:54:41
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered 'Oral (ORAL)'	Jesse Clark (b) (4)	27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	27 Apr 2021 20:54:41
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered '19 Apr 2021'	(b) (4)	
	Jesse Clark (b) (4)	27 Apr 2021 20:54:41
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	27 Apr 2021 20:54:41
	(b) (4)	

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered 'Yes (Y)'	(b) (4) Jesse Clark (b) (4)	27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	27 Apr 2021 20:54:41
	(b) (4)	



**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 16:44:22
User entered 'No (N)'	Jesse Clark (b) (4)	27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 20:54:41

**US3682040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:04:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 20:54:41

US3682040

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:04:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:17:44
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	09 Sep 2020 21:26:22

US3682040

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:04:14

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:40:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'Per CDM: Date of dose discontinuation does not match any dose dates Treatment 1 Date;01SEP2020 and VISIT 2 DAY 29; 29SEP2020. Please update or else provide clarification. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:42:43
Query 'Per CDM: Date of dose discontinuation does not match any dose dates Treatment 1 Date;01SEP2020 and VISIT 2 DAY 29; 29SEP2020. Please update or else provide clarification. Thank you' answered with 'Please clarify, - visit 2 day 29 was 29/Sep/2020. Discontinued on that day, didn't receive med.' (Site from DM).	Susan Reed (b) (4) (b) (4)	22 Oct 2020 23:54:25
User opened query 'Per CDM: Date of dose discontinuation does not match any dose dates Treatment 1 Date;01SEP2020 and VISIT 2 DAY 29; 29SEP2020. Please update or else provide clarification. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:38:08
User closed query 'Per CDM: Please confirm the 'Date of dosing discontinuation' or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:09:53
Query 'Per CDM: Please confirm the 'Date of dosing discontinuation' or else clarify. Thank you.' answered with 'This is the date the site became aware of the ae and d/c dosing.' (Site from DM).	Susan Reed (b) (4) (b) (4)	14 Oct 2020 16:49:22
User opened query 'Per CDM: Please confirm the 'Date of dosing discontinuation' or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:38:12
User entered '29 Sep 2020'	Susan Reed (b) (4) (b) (4)	09 Oct 2020 19:25:51

**US3682040**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 23:04:14**

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:40:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) Susan Reed (b) (4)	09 Oct 2020 19:25:51

US3682040

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:04:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:40:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 11:11:48
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' answered with 'reviewed and updated' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 23:02:07
User entered 'AE #2' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 23:01:57
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:15:25
User closed query 'Per CDM: thank you for the update; however, please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:43:55
Query 'Per CDM: thank you for the update; however, please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' answered with 'form updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	23 Nov 2020 18:51:49
User entered 'AE - #2' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	23 Nov 2020 18:51:31
User opened query 'Per CDM: thank you for the update; however, please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:51:55
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 05:35:01
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	18 Nov 2020 19:52:20
User entered 'AE - #2 VARICELLA ZOSTER' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	18 Nov 2020 19:52:14

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3682040**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 23:04:14**

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:42:47
User entered 'Varicella Zoster'	Susan Reed (b) (4)	09 Oct 2020 19:25:51
	(b) (4)	

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'USA-US081-2021-MRNA-1273-P301000001'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30



**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'Jesse'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'Clark'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'CA'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 00:29:33
User entered 'US'	System	07 Jan 2021 20:51:05

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Jan 2021 00:29:45
User entered '1'	System	07 Jan 2021 20:51:05

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'USA-US081-2021-MRNA-1273-P301000001'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30



**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'Jesse'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'Clark'	System	07 Jan 2021 20:50:30



**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'CA'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 00:29:33
User entered 'US'	System	07 Jan 2021 20:51:05

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Jan 2021 00:29:45
User entered '1'	System	07 Jan 2021 20:51:05

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
User entered '07/Jan/2021 15:51'	System	07 Jan 2021 20:51:05

US3682040

Folder: SAE USA-US081-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:04:14

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 00:29:33
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 20:51:05

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'USA-US081-2021-MRNA-1273-P301000001'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30



**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'No (N)'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'Jesse'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'Clark'	System	07 Jan 2021 20:50:30

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:50:58
User entered 'CA'	System	07 Jan 2021 20:50:30



**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 00:29:33
User entered 'US'	System	07 Jan 2021 20:51:05

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:04:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Jan 2021 00:29:45
User entered '1'	System	07 Jan 2021 20:51:05

**US3682040**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 23:04:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:49:46
User entered '25/Jan/2021 19:29'	System	26 Jan 2021 00:29:45

US3682040

Folder: SAE USA-US081-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 23:04:14

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:42:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Feb 2021 00:49:46
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 00:29:45