

US3472096 (Prod: Penn Prevention - (CRS))

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:46:48

All time stamps listed in this document are displayed in GMT

US3472096

Form: Participant Creation

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

[Participant ID](#)

US3472096

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

US3472096

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 02 May 2021 19:11:31

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Date of Informed Consent (<i>dd MMM yyyy</i>)	7 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" 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) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 02 May 2021 19:11:31

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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) 02 May 2021 19:11:31

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	HERNIATED DISC, L5-S1
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	SEP 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	SEBORRHEIC DERMITITIS, PERIORAL
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:27
Height (xxx.x)	190.5 cm
Weight (xxx.x)	126 kg
BMI (xxx.x)	34.72007 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 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) 02 May 2021 19:11:31

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☒ No ☐

Specify IT

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) 02 May 2021 19:11:31

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

What was the date of randomization? (dd MMM yyyy) 07 OCT 2020

What was the participant's randomization number? 116343

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) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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)	7 OCT 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:27
Temperature (xxx.x)	37.3 C
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)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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)	7 OCT 2020
Time of assessment (00:00-23:59)	13:23 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 13:23
Temperature (xxx.x)	37.1 C
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 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) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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) 7 OCT 2020

What was the treatment time? (00:00-23:59) 13:01 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 13:01

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) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 OCT 2020

Collection time (00:00-23:59)

11:55 (24 HR)

Collection date and time (derived)

7 OCT 2020 11:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Collection date (dd MMM yyyy)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:47	7 OCT 2020 11:47
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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 22:46:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 13:26

PC Open Date & Time

07 OCT 2020 13:21

PC Close Date & Time

07 OCT 2020 15:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp	07 OCT 2020 18:03
PC Open Date & Time	07 OCT 2020 16:46
PC Close Date & Time	08 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 12:35

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 16:29

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:46:48

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

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

10 OCT 2020 20:43

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 11 OCT 2020 19:06

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 OCT 2020 12:45

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

13 OCT 2020 20:48

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 8

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

14 OCT 2020 12:37

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 9

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	15 OCT 2020 20:06
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 10

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 14:29

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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

07 OCT 2020 13:26

PC Open Date & Time

07 OCT 2020 13:21

PC Close Date & Time

07 OCT 2020 15:51

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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

07 OCT 2020 17:52

PC Open Date & Time

07 OCT 2020 16:46

PC Close Date & Time

08 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:46:48

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

08 OCT 2020 12:36

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:46:48

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

09 OCT 2020 12:03

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 20:42

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 OCT 2020 19:05

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:46:48

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

12 OCT 2020 12:46

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:46:48

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

13 OCT 2020 20:48

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 13:27
PC Open Date & Time	07 OCT 2020 13:21
PC Close Date & Time	07 OCT 2020 15:51

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Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 17:53
PC Open Date & Time	07 OCT 2020 16:46
PC Close Date & Time	08 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 12:36
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

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 ☒

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 12:02
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

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 ☒

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 20:42
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 17:47
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2598

EAB) (1725)

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

		Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 12:46	
PC Open Date & Time	12 OCT 2020 12:00	
PC Close Date & Time	13 OCT 2020 11:59	

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

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 ☒

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 20:49
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 OCT 2020 12:37
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 20:06
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 14:28
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	VISIT2

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 16:02:26

Generated On: 11 Aug 2021 22:46:48

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)	04 NOV 2020
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 11:02
Temperature (xxx.x)	36.5 C
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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 16:02:26

Generated On: 11 Aug 2021 22:46:48

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	

US3472096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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 NEEDED TO LEAVE FOR ANOTHER APPOINTMENT.

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? _____

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 NOV 2020

Collection time (00:00-23:59)

11:09 (24 HR)

Collection date and time (derived)

04 NOV 2020 11:09

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Collection date (dd MMM yyyy)			04 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:06	04 NOV 2020 11:06
Nasopharyngeal Swab 2	No		

US3472096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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

PARTICIPANT ON ILLNESS
TRACK

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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

PARTICIPANT ON ILLNESS
TRACK

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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

PARTICIPANT ON ILLNESS
TRACK

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:02:26

Generated On: 11 Aug 2021 22:46:48

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 VISIT3

US3472096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

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.

US3472096

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3472096

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:26

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 DEC 2020 12:51:16
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	11 DEC 2020 16:16:52
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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	27 DEC 2020 12:07:33
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

04 JAN 2021 13:29:31

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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	08 JAN 2021 13:34:14
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

15 JAN 2021 08:47:02

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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	22 JAN 2021 07:18:53
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 07:51:51

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 22:05:46
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 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 FEB 2021 07:36:59
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <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	19 FEB 2021 07:03:08
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <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	02 MAR 2021 09:53:16
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

05 MAR 2021 07:44:47

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

12 MAR 2021 07:07:20

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 MAR 2021 12:21:35
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 12:07:30

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 10:22:49

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 09:37:14

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 07:31:07

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

23 APR 2021 07:22:24

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

30 APR 2021 06:48:04

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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="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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Please contact your study clinic immediately. Click below to confirm that you have read this message 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	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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="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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Please contact your study clinic immediately. Click below to confirm that you have read this message 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	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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°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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 460

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Please contact your study clinic immediately. Click below to confirm that you have read this message 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	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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09 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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°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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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="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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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="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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 747

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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="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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

06 DEC 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2022 23:59

US3472096

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:46:48

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		02 MAR 2021 09:53:07

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 APR 2021
Time of assessment (00:00-23:59)	12:12 (24 HR)
Vital Signs Date and Time (derived)	20 APR 2021 12:12
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 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)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3472096

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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.

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 APR 2021

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

20 APR 2021 12:20

US3472096

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Date of Contact	09 NOV 2020
Time of Contact	09:45
Date and Time of Contact (derived)	09 NOV 2020 09:45
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>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.1 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 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 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 type="radio"/>
	Mild	<input checked="" 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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US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	100.0 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 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)		

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 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 type="radio"/>
	Mild	<input checked="" 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 (3)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (4)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (4)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.1 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 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 type="radio"/>
	Mild	<input checked="" 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) 02 May 2021 19:11:27

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	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 checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	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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Form: Symptom Log (4)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	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 (5)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (5)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	100.0 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 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 type="radio"/>
	Mild	<input checked="" 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) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	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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Form: Symptom Log (5)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	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 (6)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (6)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.0 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 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 type="radio"/>
	Mild	<input checked="" 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) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	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 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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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Form: Symptom Log (7)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 type="radio"/>
	Mild	<input checked="" 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) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	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 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (9)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.0 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 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 type="radio"/>
	Mild	<input checked="" 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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	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 checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	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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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 May 2021 19:11:27

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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 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:11:27

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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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Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.4 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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Data signed: (b) (4) 02 May 2021 19:11:27

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	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 checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (11)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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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Form: Symptom Log (11)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.9 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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Data signed: (b) (4) 02 May 2021 19:11:27

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	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 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 type="radio"/>
	Mild	<input checked="" 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 09 Nov 2020

Form: Symptom Log (11)

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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 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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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Form: Symptom Log (12)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.2 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 (12)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 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 type="radio"/>
	Mild	<input checked="" 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 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (13)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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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Form: Symptom Log (13)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	20 NOV 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 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 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 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 type="radio"/>
	Mild	<input checked="" 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 (13)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (14)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 type="checkbox"/>
Day 13	<input checked="" 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 (14)

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	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 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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	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 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 type="radio"/>
	Mild	<input checked="" 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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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 (15)

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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 type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" 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 (15)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	98 %	
O2 Saturation Units	%	
Temperature	97.2 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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	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 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 type="radio"/>
	Mild	<input checked="" 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 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 May 2021 19:11:27

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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 (16)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" 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 (16)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	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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	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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Form: Symptom Log (16)

Data signed: (b) (4) 02 May 2021 19:11:27

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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 (17)

Data signed: (b) (4) 02 May 2021 19:11:27

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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 type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" 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 (17)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	99 %	
O2 Saturation Units	%	
Temperature	98.2 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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	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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Form: Symptom Log (17)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (18)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 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 checked="" 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 (18)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	99 %	
O2 Saturation Units	%	
Temperature	98.4 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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EAB) (1725)

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Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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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EAB) (1725)

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Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 (19)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 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 checked="" 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 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	99 %	
O2 Saturation Units	%	
Temperature	98.2 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 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 checked="" 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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	97.6 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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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 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 checked="" 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 09 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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	98 %	
O2 Saturation Units	%	
Temperature	98.2 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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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	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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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 09 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Date of Visit 10 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Date of Test 10 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

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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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 May 2021 19:11:28

Generated On: 11 Aug 2021 22:46:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 NOV 2020
Day 5	Yes	13 NOV 2020
Day 7	Yes	16 NOV 2020
Day 9	Yes	18 NOV 2020
Day 14	Yes	23 NOV 2020
Day 21	Yes	30 NOV 2020
Day 28	No	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 NOV 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 13:15
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99.1 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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 NOV 2020

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

US3472096

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 NOV 2020

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 SICKD28

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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.

US3472096

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

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

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

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

Visit date (dd MMM yyyy)	5 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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US3472096

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

Form: Unblinding

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Date of updated informed consent (<i>dd MMM yyyy</i>)	5 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>)	5 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

US3472096

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

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

US3472096

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

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)	5 FEB 2021
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 11:02
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

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)	5 FEB 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 14:15
Temperature (xxx.x)	36.8 C
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

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

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

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

US3472096

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

Form: Exposure

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

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) 5 FEB 2021

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

Treatment Date and Time (derived) 5 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

US3472096

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 FEB 2021

Collection time (00:00-23:59)

11:12 (24 HR)

Collection date and time (derived)

5 FEB 2021 11:12

US3472096

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 FEB 2021
Collection time (00:00 - 23:59)	11:06
Collection Date and Time (derived)	5 FEB 2021 11:06

US3472096

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

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

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)	9 MAR 2021
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 11:30
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

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)	9 MAR 2021
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 13:39
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 MAR 2021

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

US3472096

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

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) 9 MAR 2021

What was the treatment time? (00:00-23:59) 13:09 (24 HR)

Treatment Date and Time (derived) 9 MAR 2021 13:09

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

US3472096

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 APR 2021
Time of assessment (00:00-23:59)	12:12 (24 HR)
Vital Signs Date and Time (derived)	20 APR 2021 12:12
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 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)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3472096

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 APR 2021

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

20 APR 2021 12:20

US3472096

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Mar 2021 16:11:29

Generated On: 11 Aug 2021 22:46:48

AEID	USA-US122-2020-MRNA-1273-P30 1000003
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	09 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)	29 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Mar 2021 16:11:29

Generated On: 11 Aug 2021 22:46:48

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 checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Mar 2021 16:11:29

Generated On: 11 Aug 2021 22:46:48

AEID	
Adverse event	ELEVATED BLOOD PRESSURE
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)	5 FEB 2021
Start time (00:00-23:59)	12:00 (24 HR)
AE start date and time (derived)	5 FEB 2021 12:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="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 (7)

Data signed: (b) (4) 29 Mar 2021 16:11:29

Generated On: 11 Aug 2021 22:46:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT HAS SCHEDULED AN APPOINTMENT WITH A CARDIOLOGIST FOR MARCH 25TH, 2021
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)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

Yes ☒

No ☐

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

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN

Dose per administration 400

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) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

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

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication TEGRETOL

Prophylaxis Yes ☐
No ☒

Indication BPD

Dose per administration 400

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) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication BPD

Dose per administration 200

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) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	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)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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Name of Medication DYMISTA NASAL SPRAY

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 2

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

If dose unit is Other, specify SPRAYS

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) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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 (5)

Data signed: (b) (4) 02 May 2021 19:11:26

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Name of Medication ALLERGY SHOTS

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☒
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	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 2016	
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 checked="" 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 (6)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication KETOCONAZOLE CREAM

Prophylaxis Yes ☐
No ☒

Indication SEBORRHEIC DERMITITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 (6)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	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 2017	
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 (7)

Data signed: (b) (4) 02 May 2021 19:11:26

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Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	Intramuscular	<input checked="" 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)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
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 (8)

Data signed: (b) (4) 02 May 2021 19:11:26

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Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 5000

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 (8)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 May 2021 19:11:26

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Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

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 (9)

Data signed: (b) (4) 02 May 2021 19:11:26

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	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 May 2021 19:11:26

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Name of Medication ZINC LOZENGES

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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 (10)

Data signed: (b) (4) 02 May 2021 19:11:26

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	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 500

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 (11)

Data signed: (b) (4) 02 May 2021 19:11:26

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	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)		12 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) 12 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 (12)

Data signed: (b) (4) 02 May 2021 19:11:26

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 180

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 (12)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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)		12 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)		29 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 (13)

Data signed: (b) (4) 02 May 2021 19:11:26

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 650

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 (13)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	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)	6 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 FEB 2021		
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 (14)

Data signed: (b) (4) 02 May 2021 19:11:26

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication ELEVATED BLOOD PRESSURE

Dose per administration 20

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 (14)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	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)	18 MAR 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"/>

US3472096

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 May 2021 19:11:28

Generated On: 11 Aug 2021 22:46:48

Date of dosing discontinuation (dd MMM yyyy) 09 NOV 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

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

US3472096

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:46:48

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 ☐

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

SAEID	USA-US122-2020-MRNA-1273-P301000003
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

SAEID	USA-US122-2020-MRNA-1273-P301000003
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 14:54
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

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

SAEID	USA-US122-2020-MRNA-1273-P301000003
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/NOV/2020 21:40
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

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

SAEID	USA-US122-2020-MRNA-1273-P301000003
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/DEC/2020 13:56
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

US3472096 (Prod: Penn Prevention - (CRS))

US3472096

Form: Participant Creation

Generated On: 11 Aug 2021 22:46:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:06
User entered 'US3472096'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 15:22:51

US3472096

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:31
User entered 'Yes (Y)'		07 Oct 2020 17:12:24

US3472096

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:31
User entered '07 OCT 2020'	RWS_ENDPOINT	07 Oct 2020 15:22:53
	ENDPOINT (b) (4)	

US3472096

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[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 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:31
User entered 'Clinic (Clinic)'		07 Oct 2020 17:12:24

US3472096

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'SCRN'	System	07 Oct 2020 17:12:24

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered (b) (6) 1978'	RWS_ENDPOINT	07 Oct 2020 15:22:54
	ENDPOINT (b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '42'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'YEARS'	System	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '42'	System	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered 'Male (M)'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered 'I'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered 'l'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:35:40
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Oct 2020'	System	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2020'	System	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:35:40
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 17:32:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 17:32:54
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	Jie Ho (b) (4)	07 Oct 2020 17:32:54
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 17:12:35
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered 'Yes (Y)'		07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered empty.		07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered empty.		07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered 'No (N)'		07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:35:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 15:22:53

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'I'	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:45
User entered 'Yes (Y)'		07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:46:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:50
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:42:40
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Psychiatric disorders, HLGT: Personality disorders and disturbances in behaviour, HLT: Personality disorders with dramatic behaviour (Cluster B), PT: Borderline personality disorder, LLT: Borderline personality disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:48:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:48:56
Data point term sent to Coder	System	07 Oct 2020 18:43:54
User entered 'Borderline personality disorder'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Jan 2000'	Petra Alexander (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:43:21
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:43:21
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:43:21
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 2000'	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2000'	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
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: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 13:30:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 13:30:40
Data point term sent to Coder	System	07 Oct 2020 18:45:05
User entered 'Herniated disc, L5-S1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 2005'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Sep 2005'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Sep 2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:12
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).		13 Jan 2021 21:05:03
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Procedure due to Cholecystitis, which has been updated in MH' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:30:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:29:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:29:14
Data point term sent to Coder	System	12 Jan 2021 17:28:06
DataPoint Un-verified.	(b) (4), (b) (6)	12 Jan 2021 17:27:28
Coding entries removed.		12 Jan 2021 17:27:28
User entered 'cholecystectomy' reason for change: Per Query Resolution		12 Jan 2021 17:27:28
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).		12 Jan 2021 06:35:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 18:51:16

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EAB) (1725)

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	07 Oct 2020 18:51:16
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	07 Oct 2020 18:45:06
User entered 'Cholecystectomy'	Petra Alexander (b) (4)	07 Oct 2020 18:45:04
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Oct 2019'	Petra Alexander (b) (4)	07 Oct 2020 18:45:04
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:45:04
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).		13 Nov 2020 04:38:06
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	27 Oct 2020 02:53:14
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	27 Oct 2020 02:52:40
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:31:31
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:04

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:35:55
User entered 'un Oct 2019' reason for change: Data Entry Error	Jie Ho (b) (4)	27 Oct 2020 02:52:40
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:45:04

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:45:04

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Oct 2019'	System	07 Oct 2020 18:45:04

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2019'	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Oct 2019'	System	27 Oct 2020 02:52:40
User entered empty.	System	07 Oct 2020 18:45:04

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2019'	System	27 Oct 2020 02:52:40
User entered empty.	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 18:54:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 18:54:09
Data point term sent to Coder	System	07 Oct 2020 18:46:09
User entered 'Seasonal allergic rhinitis'	Petra Alexander (b) (4)	07 Oct 2020 18:45:33
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 1996'	Petra Alexander (b) (4)	07 Oct 2020 18:45:33
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:45:33
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:45:33
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:45:33
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:45:33
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 1996'	System	07 Oct 2020 18:45:33

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '1996'	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Seborrheic dermatitis, LLT: Seborrheic dermatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:59:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:59:23
Data point term sent to Coder	System	07 Oct 2020 18:47:13
User entered 'Seborrheic dermititis, perioral'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 2017'	Petra Alexander (b) (4)	07 Oct 2020 18:46:17
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:46:17
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:46:17
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:46:17
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 2017'	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2017'	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:56:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:56:15
Data point term sent to Coder	System	07 Oct 2020 18:47:13
User entered 'obesity'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:46:34
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:46:34
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:46:34
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 2020'	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2020'	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:24:12
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:29:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:29:55
Data point term sent to Coder	System	12 Jan 2021 17:29:11
User entered 'Cholecystitis'	(b) (4), (b) (6)	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:12
User entered 'UN Sep 2019'		12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:24:12
User entered '0'	(b) (4), (b) (6)	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:12
User entered 'No (N)'		12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:24:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Jan 2021 17:28:44
User entered 'UN Oct 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 17:28:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Jan 2021 17:28:25
User entered 'UN ' (non-conformant).	(b) (4), (b) (6)	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:12
User entered '0'		12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Sep 2019'	System	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2019'	System	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Oct 2019'	System	12 Jan 2021 17:28:44
User entered empty.	System	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2019'	System	12 Jan 2021 17:28:44
User entered empty.	System	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '11:27'	Petra Alexander (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '7 Oct 2020 11:27'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '190.5' cm	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
DataPoint set to visible.	(b) (4)	
	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '126' kg	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
DataPoint set to visible.	(b) (4)	
	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '34.72007'	System	07 Oct 2020 18:37:15
DataPoint set to visible.	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'kg/m2'	System	07 Oct 2020 18:37:15
DataPoint set to visible.	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'bpm'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'breaths/min'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'mmHg'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'mmHg'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41

US3472096

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:29
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:37:47
	(b) (4)	

US3472096

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:29
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:37:47
	(b) (4)	

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

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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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

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[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

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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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

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[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered 'IT'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:36:35
User entered 'l'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:01
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:39:17

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:37:01
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:39:17

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:01
User entered 'Clinic (Clinic)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:39:17

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'VISIT1'	System	07 Oct 2020 18:39:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:37:06
User entered '07 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 16:12:41

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:37:06
User entered '116343'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 16:12:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:37:06
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 16:12:41

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:47:36
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:47:36
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:47:36
DataPoint set to visible.	(b) (4) System	07 Oct 2020 17:32:54

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User accepted default value 'Pre-Dose (PREDOSE)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:37:15
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '11:27'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 11:27'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '37.3' C	Petra Alexander (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:37:15
User entered 'Oral (Oral)'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '75'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'bpm'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '16'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'breaths/min'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '165'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'mmHg'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '93'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'mmHg'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User accepted default value 'Post-Dose (POSTDOSE)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '13:23'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 13:23'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '37.1' C	Petra Alexander (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Oral (Oral)'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '69'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'bpm'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '16'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'breaths/min'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '155'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'mmHg'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '88'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'mmHg'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:37:21
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:41:01

US3472096

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:21
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:01

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered empty.		07 Oct 2020 17:13:05

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered empty.		07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered '7 Oct 2020'		07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered '13:01'		07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 13:01'	System	07 Oct 2020 17:13:05

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered 'Right Arm (RIGHT ARM)'		07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
DataPoint Verified.		19 Nov 2020 15:37:27
User entered 'ONCE'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:34
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:14

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:34
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:41:14
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:34
User entered '11:55'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:14

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 11:55'	System	07 Oct 2020 18:41:14

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered '11:47'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 11:47'	System	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered empty.	System	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:37:46
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:41:43
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'I'	System	07 Oct 2020 18:41:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:25:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered 'Yes (Y)'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:25:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered '98.8'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered 'No (N)'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:04', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered '07 Oct 2020 13:26'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 13:21'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 15:51'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:02:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered 'Yes (Y)'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:03:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered '98.5'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:03:05', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered 'No (N)'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:03:08', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered '07 Oct 2020 18:03'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 16:46'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 2'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:34:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered 'Yes (Y)'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee' User entered '97.5'	System	08 Oct 2020 16:35:51
	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered 'No (N)'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered '08 Oct 2020 12:35'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 3'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:28:48', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered 'Yes (Y)'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:29:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered '98.2'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:29:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered 'No (N)'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:29:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1' User entered '09 Oct 2020 16:29'	System	09 Oct 2020 20:29:58
	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 4'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb'	System	11 Oct 2020 00:43:44
User entered 'Yes (Y)'	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:27', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb' User entered '98.3'	System	11 Oct 2020 00:43:44
	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:41', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb'	System	11 Oct 2020 00:43:44
User entered 'No (N)'	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb'	System	11 Oct 2020 00:43:44
User entered '10 Oct 2020 20:43'	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 5'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered 'Yes (Y)'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '98.3'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered 'Yes (Y)'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:54:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	11 Oct 2020 23:06:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '1'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '0'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '11 Oct 2020 19:06'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 6'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered 'Yes (Y)'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:40', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '97.3'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered 'Yes (Y)'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Oct 2020 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '1'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '0'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:48', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '12 Oct 2020 12:45'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 7'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered 'Yes (Y)'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '98.2'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:27', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered 'Yes (Y)'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Oct 2020 00:48:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '1'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '0'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:32', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '13 Oct 2020 20:48'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	12 Oct 2020 16:45:50
User entered 'Day 8'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered 'Yes (Y)'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5' User entered '97.3'	System	14 Oct 2020 16:37:57
	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered 'Yes (Y)'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Oct 2020 19:39:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '1'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '0'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '14 Oct 2020 12:37'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	14 Oct 2020 00:48:37
User entered 'Day 9'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:21', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211' User entered '98.2'	System	16 Oct 2020 00:06:45
	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Oct 2020 00:06:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '1'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '0'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:38', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '15 Oct 2020 20:06'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	14 Oct 2020 16:37:57
User entered 'Day 10'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f'	System	16 Oct 2020 18:29:08
User entered 'Yes (Y)'	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f' User entered '98.4'	System	16 Oct 2020 18:29:08
	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:29:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f'	System	16 Oct 2020 18:29:08
User entered 'No (N)'	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:29:03', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f' User entered '16 Oct 2020 14:29'	System	16 Oct 2020 18:29:08
	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'No (N)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'No (N)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'None (1)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered '07 Oct 2020 13:26'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 13:21'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 15:51'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:18', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'None (1)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'No (N)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'No (N)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:40', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'None (1)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:42', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered '07 Oct 2020 17:52'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 16:46'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 2'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'None (1)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:46:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:11', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'No (N)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'No (N)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:26', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'None (1)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered '08 Oct 2020 12:36'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 3'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:58', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'None (1)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:46:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'No (N)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'No (N)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:15', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'None (1)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:17', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered '09 Oct 2020 12:03'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 4'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:41', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'None (1)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:46:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'No (N)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'No (N)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'None (1)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered '10 Oct 2020 20:42'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 5'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'None (1)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'No (N)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'No (N)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'None (1)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:38', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered '11 Oct 2020 19:05'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 6'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'None (1)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:46:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'No (N)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:56', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'No (N)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:58', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'None (1)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:01', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered '12 Oct 2020 12:46'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 7'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'None (1)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:46:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:38', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'No (N)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:40', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'No (N)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:46:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:42', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'None (1)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered '13 Oct 2020 20:48'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:16', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:21', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:23', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'No (N)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:32', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered '07 Oct 2020 13:27'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 13:21'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 15:51'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e' User entered 'None (0)'	System	07 Oct 2020 21:53:15
	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:56', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:01', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:03', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:05', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:10', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'No (N)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e' User entered '07 Oct 2020 17:53'	System	07 Oct 2020 21:53:15
	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 16:46'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 2'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:42', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'No (N)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:51', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered '08 Oct 2020 12:36'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 3'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:20', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'Some interference with activity (2)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'No (N)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered '09 Oct 2020 12:02'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 4'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:23', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'Some interference with activity (2)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:27', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'No (N)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:37', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered '10 Oct 2020 20:42'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 5'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:17', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:20', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:22', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:26', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'No (N)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520' User entered '11 Oct 2020 17:47'	System	11 Oct 2020 21:47:38
	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 6'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:04', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:07', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'No interference with activity (1)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:09', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:11', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:13', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:21', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'No (N)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:23', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered '12 Oct 2020 12:46'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 7'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:51', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:55', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:49:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'No (N)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:49:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered '13 Oct 2020 20:49'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	12 Oct 2020 16:45:50
User entered 'Day 8'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:32', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '48f30f7b-4f8d-4c5e-8a4f-d3d04c5543ce'	System	14 Oct 2020 16:37:37
User entered 'No (N)'	System	14 Oct 2020 16:37:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '48f30f7b-4f8d-4c5e-8a4f-d3d04c5543ce'	System	14 Oct 2020 16:37:37
User entered '14 Oct 2020 12:37'	System	14 Oct 2020 16:37:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	14 Oct 2020 00:48:37
User entered 'Day 9'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'afeffa1e-60d2-4ae9-b38c-eb3702e25261'	System	16 Oct 2020 00:06:56
User entered 'No (N)'	System	16 Oct 2020 00:06:56

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'afeffa1e-60d2-4ae9-b38c-eb3702e25261'	System	16 Oct 2020 00:06:56
User entered '15 Oct 2020 20:06'	System	16 Oct 2020 00:06:56

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	14 Oct 2020 16:37:57
User entered 'Day 10'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '275b81b5-ff55-4d47-8517-b1cd758f5387'	System	16 Oct 2020 18:28:51
User entered 'No (N)'	System	16 Oct 2020 18:28:51

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '275b81b5-ff55-4d47-8517-b1cd758f5387'	System	16 Oct 2020 18:28:51
User entered '16 Oct 2020 14:28'	System	16 Oct 2020 18:28:51

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:37:57

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:38:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 15:38:18
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered 'Contact Made (CONTACT MADE)'		14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered empty.		14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:38:23
User entered 'Yes (Y)'		14 Oct 2020 22:47:54

US3472096

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User entered 'I'	System	14 Oct 2020 22:47:54

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered 'Yes (Y)'		21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered '21 Oct 2020'		21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered 'Contact Made (CONTACT MADE)'		21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered empty.		21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:01
User entered 'Yes (Y)'		21 Oct 2020 17:56:35

US3472096

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User entered 'I'	System	21 Oct 2020 17:56:35

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered 'Yes (Y)'		30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	19 Nov 2020 23:00:07
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered 'Contact Made (CONTACT MADE)'		30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered empty.		30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:11
User entered 'Yes (Y)'		30 Oct 2020 20:51:52

US3472096

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User entered 'I'	System	30 Oct 2020 20:51:52

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:23
User entered 'Yes (Y)'		04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:23
User entered '04 Nov 2020'		04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[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 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:23
User entered 'Clinic (Clinic)'		04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'VISIT2'	System	04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User accepted default value 'Pre-Dose (PREDOSE)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '04 Nov 2020'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '11:02'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered '04 Nov 2020 11:02'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '36.5' C	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered 'Oral (Oral)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '69'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'bpm'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '17'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'breaths/min'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '170'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'mmHg'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '91'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'mmHg'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User accepted default value 'Post-Dose (POSTDOSE)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered 'No (N)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:34
User entered 'Yes (Y)'		04 Nov 2020 16:26:15

US3472096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:34
User entered '04 Nov 2020'		04 Nov 2020 16:26:15

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered 'No (N)'	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered 'Other (OTHER)'	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered 'Participant needed to leave for another appointment.'	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
DataPoint Verified.		02 Feb 2021 23:58:40
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:46
User entered 'Yes (Y)'		04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	02 Feb 2021 23:58:46
User entered '04 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:46
User entered '11:09'		04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered '04 Nov 2020 11:09'	System	04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered '04 Nov 2020'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered 'Yes (Y)'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered '11:06'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered '04 Nov 2020 11:06'	System	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered 'No (N)'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered empty.		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered empty.	System	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:59:01
User entered 'Yes (Y)'		04 Nov 2020 16:26:50

US3472096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'I'	System	04 Nov 2020 16:26:50

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:43
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:11:18

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:43
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:11:18

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:43
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:11:18

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:43
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:11:18

US3472096

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:50
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:36

US3472096

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered 'I'	System	09 Dec 2020 16:12:36

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:55
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:45

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:55
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:45

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:55
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:45

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:55
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:45

US3472096

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:59
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:49

US3472096

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered 'I'	System	09 Dec 2020 16:12:49

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:18:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:58

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:18:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:58

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:18:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:58

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:18:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:58

US3472096

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:18:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:13:01

US3472096

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered 'I'	System	09 Dec 2020 16:13:01

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
DataPoint Verified.		08 Apr 2021 14:18:31
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Dec 2020 17:02:54

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
DataPoint Verified.		08 Apr 2021 14:18:31
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	27 Dec 2020 17:02:54

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[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 20:38:46
DataPoint Verified.		08 Apr 2021 14:18:31
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 17:02:54

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'VISIT3'	System	27 Dec 2020 17:02:54

US3472096

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
DataPoint Verified.		08 Apr 2021 14:18:38
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Dec 2020 17:03:07

US3472096

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered '1'	System	27 Dec 2020 17:03:07

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2020-12-08T12:50:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9bfd55ec-9fb0-473b-a859-eb5c9766c55e'	System	08 Dec 2020 17:51:20
User entered 'No (N)'	System	08 Dec 2020 17:51:20

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2020-12-08T12:51:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9bfd55ec-9fb0-473b-a859-eb5c9766c55e'	System	08 Dec 2020 17:51:20
User entered 'No (N)'	System	08 Dec 2020 17:51:20

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-12-08T12:51:16', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9bfd55ec-9fb0-473b-a859-eb5c9766c55e'	System	08 Dec 2020 17:51:20
User entered '08 Dec 2020 12:51:16'	System	08 Dec 2020 17:51:20

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2020-12-11T16:16:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6d9b402c-2133-4172-b100-6316de939278'	System	11 Dec 2020 21:16:55
User entered 'No (N)'	System	11 Dec 2020 21:16:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2020-12-11T16:16:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6d9b402c-2133-4172-b100-6316de939278'	System	11 Dec 2020 21:16:55
User entered 'No (N)'	System	11 Dec 2020 21:16:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-12-11T16:16:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6d9b402c-2133-4172-b100-6316de939278'	System	11 Dec 2020 21:16:55
User entered '11 Dec 2020 16:16:52'	System	11 Dec 2020 21:16:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2020-12-27T12:07:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c07db9af-f212-471b-8d7d-358015ae4c01'	System	27 Dec 2020 17:07:39
User entered 'No (N)'	System	27 Dec 2020 17:07:39

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2020-12-27T12:07:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c07db9af-f212-471b-8d7d-358015ae4c01'	System	27 Dec 2020 17:07:39
User entered 'No (N)'	System	27 Dec 2020 17:07:39

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-12-27T12:07:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c07db9af-f212-471b-8d7d-358015ae4c01'	System	27 Dec 2020 17:07:39
User entered '27 Dec 2020 12:07:33'	System	27 Dec 2020 17:07:39

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-04T13:29:26', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bb21ec81-795c-4494-aec6-aad4f76d8d8d'	System	04 Jan 2021 18:29:34
User entered 'No (N)'	System	04 Jan 2021 18:29:34

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-04T13:29:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bb21ec81-795c-4494-aec6-aad4f76d8d8d'	System	04 Jan 2021 18:29:34
User entered 'No (N)'	System	04 Jan 2021 18:29:34

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-04T13:29:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bb21ec81-795c-4494-aec6-aad4f76d8d8d'	System	04 Jan 2021 18:29:34
User entered '04 Jan 2021 13:29:31'	System	04 Jan 2021 18:29:34

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-08T13:34:09', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '96408f24-1e10-4a17-831b-f8a105e08597'	System	08 Jan 2021 18:34:15
User entered 'No (N)'	System	08 Jan 2021 18:34:15

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-08T13:34:11', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '96408f24-1e10-4a17-831b-f8a105e08597'	System	08 Jan 2021 18:34:15
User entered 'No (N)'	System	08 Jan 2021 18:34:15

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-08T13:34:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '96408f24-1e10-4a17-831b-f8a105e08597'	System	08 Jan 2021 18:34:15
User entered '08 Jan 2021 13:34:14'	System	08 Jan 2021 18:34:15

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-15T08:46:56', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '46a19432-19f1-4ba2-9c20-248f0c2c3e32'	System	15 Jan 2021 13:47:06
User entered 'No (N)'	System	15 Jan 2021 13:47:06

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-15T08:46:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '46a19432-19f1-4ba2-9c20-248f0c2c3e32'	System	15 Jan 2021 13:47:06
User entered 'No (N)'	System	15 Jan 2021 13:47:06

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-15T08:47:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '46a19432-19f1-4ba2-9c20-248f0c2c3e32'	System	15 Jan 2021 13:47:06
User entered '15 Jan 2021 08:47:02'	System	15 Jan 2021 13:47:06

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-22T07:18:48', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '0c506f84-708c-45c9-bc48-b618bc6d9e17'	System	22 Jan 2021 12:18:54
User entered 'No (N)'	System	22 Jan 2021 12:18:54

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-22T07:18:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '0c506f84-708c-45c9-bc48-b618bc6d9e17'	System	22 Jan 2021 12:18:54
User entered 'No (N)'	System	22 Jan 2021 12:18:54

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-22T07:18:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '0c506f84-708c-45c9-bc48-b618bc6d9e17' User entered '22 Jan 2021 07:18:53'	System	22 Jan 2021 12:18:54
	System	22 Jan 2021 12:18:54

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-29T07:51:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '68d5a97f-29b9-41b0-ae5a-5970781839e5'	System	29 Jan 2021 12:51:55
User entered 'No (N)'	System	29 Jan 2021 12:51:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-29T07:51:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '68d5a97f-29b9-41b0-ae5a-5970781839e5'	System	29 Jan 2021 12:51:55
User entered 'No (N)'	System	29 Jan 2021 12:51:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-29T07:51:51', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '68d5a97f-29b9-41b0-ae5a-5970781839e5' User entered '29 Jan 2021 07:51:51'	System	29 Jan 2021 12:51:55
	System	29 Jan 2021 12:51:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-02-05T22:05:41', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '28f76be3-5acf-462c-bb4e-8d4691f20433'	System	06 Feb 2021 03:06:18
User entered 'No (N)'	System	06 Feb 2021 03:06:18

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-02-05T22:05:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '28f76be3-5acf-462c-bb4e-8d4691f20433'	System	06 Feb 2021 03:06:18
User entered 'No (N)'	System	06 Feb 2021 03:06:18

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-02-05T22:05:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '28f76be3-5acf-462c-bb4e-8d4691f20433'	System	06 Feb 2021 03:06:18
User entered '05 Feb 2021 22:05:46'	System	06 Feb 2021 03:06:18

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-02-12T07:36:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '835adfb5-877b-450b-8407-94643e6d942d'	System	12 Feb 2021 12:37:04
User entered 'No (N)'	System	12 Feb 2021 12:37:04

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-02-12T07:36:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '835adfb5-877b-450b-8407-94643e6d942d'	System	12 Feb 2021 12:37:04
User entered 'No (N)'	System	12 Feb 2021 12:37:04

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-02-12T07:36:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '835adfb5-877b-450b-8407-94643e6d942d'	System	12 Feb 2021 12:37:04
User entered '12 Feb 2021 07:36:59'	System	12 Feb 2021 12:37:04

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-02-19T07:03:01', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '7efce5c0-20ba-4c0e-a739-a5f1a528f02e'	System	19 Feb 2021 17:10:40
User entered 'No (N)'	System	19 Feb 2021 17:10:40

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-02-19T07:03:04', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '7efce5c0-20ba-4c0e-a739-a5f1a528f02e'	System	19 Feb 2021 17:10:40
User entered 'No (N)'	System	19 Feb 2021 17:10:40

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-02-19T07:03:08', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '7efce5c0-20ba-4c0e-a739-a5f1a528f02e'	System	19 Feb 2021 17:10:40
User entered '19 Feb 2021 07:03:08'	System	19 Feb 2021 17:10:40

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-02T09:53:12-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '322e17a4-153e-4fc7-8764-af3cabe7fe70'	System	02 Mar 2021 14:53:19
User entered 'No (N)'	System	02 Mar 2021 14:53:19

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-03-02T09:53:14-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '322e17a4-153e-4fc7-8764-af3cabe7fe70'	System	02 Mar 2021 14:53:19
User entered 'No (N)'	System	02 Mar 2021 14:53:19

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-02T09:53:16-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '322e17a4-153e-4fc7-8764-af3cabe7fe70'	System	02 Mar 2021 14:53:19
User entered '02 Mar 2021 09:53:16'	System	02 Mar 2021 14:53:19

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-05T07:44:43-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '1b9338a5-c0b0-4d18-b875-39817f66aabe'	System	05 Mar 2021 12:44:48
User entered 'No (N)'	System	05 Mar 2021 12:44:48

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-03-05T07:44:46-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '1b9338a5-c0b0-4d18-b875-39817f66aabe'	System	05 Mar 2021 12:44:48
User entered 'No (N)'	System	05 Mar 2021 12:44:48

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-05T07:44:47-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '1b9338a5-c0b0-4d18-b875-39817f66aabe' User entered '05 Mar 2021 07:44:47'	System	05 Mar 2021 12:44:48
	System	05 Mar 2021 12:44:48

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-12T07:07:16-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '782377b7-4c9a-4d05-a233-be4814020117'	System	12 Mar 2021 12:07:24
User entered 'No (N)'	System	12 Mar 2021 12:07:24

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-03-12T07:07:18-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '782377b7-4c9a-4d05-a233-be4814020117'	System	12 Mar 2021 12:07:24
User entered 'No (N)'	System	12 Mar 2021 12:07:24

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-12T07:07:20-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '782377b7-4c9a-4d05-a233-be4814020117'	System	12 Mar 2021 12:07:24
User entered '12 Mar 2021 07:07:20'	System	12 Mar 2021 12:07:24

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-19T12:21:16-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'Yes (Y)'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-03-19T12:21:09-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'No (N)'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-19T12:21:20-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'No (N)'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-19T12:21:26-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'Yes (Y)'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Please 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 (12282b35a699ff53)', Time: '2021-03-19T12:21:32-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-19T12:21:35-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered '19 Mar 2021 12:21:35'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-03-30T12:07:26-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '36352b55-7c7d-47b0-8101-1e7aa0649bbd'	System	30 Mar 2021 16:14:10
User entered 'No (N)'	System	30 Mar 2021 16:14:10

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-03-30T12:07:28-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '36352b55-7c7d-47b0-8101-1e7aa0649bbd'	System	30 Mar 2021 16:14:10
User entered 'No (N)'	System	30 Mar 2021 16:14:10

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-03-30T12:07:30-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '36352b55-7c7d-47b0-8101-1e7aa0649bbd'	System	30 Mar 2021 16:14:10
User entered '30 Mar 2021 12:07:30'	System	30 Mar 2021 16:14:10

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-06T10:22:43-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bdbe1b8b-67f4-4b41-8e9b-9aae70a41ab3'	System	06 Apr 2021 14:22:55
User entered 'No (N)'	System	06 Apr 2021 14:22:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-06T10:22:47-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bdbelb8b-67f4-4b41-8e9b-9aae70a41ab3'	System	06 Apr 2021 14:22:55
User entered 'No (N)'	System	06 Apr 2021 14:22:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-06T10:22:49-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bdbelb8b-67f4-4b41-8e9b-9aae70a41ab3'	System	06 Apr 2021 14:22:55
User entered '06 Apr 2021 10:22:49'	System	06 Apr 2021 14:22:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-13T09:37:09-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8676cbd6-0c28-47e2-ab22-794c261fe3f5'	System	13 Apr 2021 13:37:16
User entered 'No (N)'	System	13 Apr 2021 13:37:16

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-13T09:37:11-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8676cbd6-0c28-47e2-ab22-794c261fe3f5'	System	13 Apr 2021 13:37:16
User entered 'No (N)'	System	13 Apr 2021 13:37:16

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-13T09:37:14-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8676cbd6-0c28-47e2-ab22-794c261fe3f5'	System	13 Apr 2021 13:37:16
User entered '13 Apr 2021 09:37:14'	System	13 Apr 2021 13:37:16

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-16T07:31:02-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '23c2cbb8-0596-484e-93bc-89006cbea2d8' User entered 'No (N)'	System	16 Apr 2021 11:31:09
	System	16 Apr 2021 11:31:09

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-16T07:31:04-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '23c2cbb8-0596-484e-93bc-89006cbea2d8'	System	16 Apr 2021 11:31:09
User entered 'No (N)'	System	16 Apr 2021 11:31:09

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-16T07:31:07-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '23c2cbb8-0596-484e-93bc-89006cbea2d8'	System	16 Apr 2021 11:31:09
User entered '16 Apr 2021 07:31:07'	System	16 Apr 2021 11:31:09

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-23T07:22:21-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8335883c-bbfd-4de5-8025-e9e4413bb0f1'	System	23 Apr 2021 11:22:27
User entered 'No (N)'	System	23 Apr 2021 11:22:27

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-23T07:22:23-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8335883c-bbfd-4de5-8025-e9e4413bb0f1'	System	23 Apr 2021 11:22:27
User entered 'No (N)'	System	23 Apr 2021 11:22:27

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-23T07:22:24-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8335883c-bbfd-4de5-8025-e9e4413bb0f1' User entered '23 Apr 2021 07:22:24'	System	23 Apr 2021 11:22:27
	System	23 Apr 2021 11:22:27

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-30T06:48:00-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '348a9f95-98af-496e-95d6-e7367388120d' User entered 'No (N)'	System	30 Apr 2021 10:48:07

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-30T06:48:01-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '348a9f95-98af-496e-95d6-e7367388120d' User entered 'No (N)'	System	30 Apr 2021 10:48:07

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-30T06:48:04-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '348a9f95-98af-496e-95d6-e7367388120d' User entered '30 Apr 2021 06:48:04'	System	30 Apr 2021 10:48:07
	System	30 Apr 2021 10:48:07

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:46:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:48:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-02T09:53:05-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2698389f-5988-4853-b1e4-2ddf84857c06'	System	02 Mar 2021 14:53:09
User entered 'No (N)'	System	02 Mar 2021 14:53:09

US3472096

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:46:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:48:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-02T09:53:07-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2698389f-5988-4853-b1e4-2ddf84857c06'	System	02 Mar 2021 14:53:09
User entered '02 Mar 2021 09:53:07'	System	02 Mar 2021 14:53:09

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:58:33
User entered 'Yes (Y)'		27 Dec 2020 17:15:32

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:58:33
User entered '27 Dec 2020'		27 Dec 2020 17:15:32

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4)	03 Feb 2021 05:58:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Dec 2020 17:15:32

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 05:58:33
User entered empty.		27 Dec 2020 17:15:32

US3472096

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:58:37
User entered 'Yes (Y)'		27 Dec 2020 17:15:37

US3472096

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered 'I'	System	27 Dec 2020 17:15:37

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:15:38
User entered 'Yes (Y)'		30 Jan 2021 21:02:00

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:15:38
User entered '30 Jan 2021'	(b) (4), (b) (6)	30 Jan 2021 21:02:00

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:15:38
User entered 'Contact Made (CONTACT MADE)'		30 Jan 2021 21:02:00

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:15:38
User entered empty.		30 Jan 2021 21:02:00

US3472096

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:15:44
User entered 'Yes (Y)'		30 Jan 2021 21:02:18

US3472096

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User entered 'I'	System	30 Jan 2021 21:02:18

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:16:17
User entered 'No (N)'	(b) (4), (b) (6)	18 Mar 2021 14:41:54

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:17
User entered empty.		18 Mar 2021 14:41:54

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:17
User entered empty.		18 Mar 2021 14:41:54

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:17
User entered empty.		18 Mar 2021 14:41:54

US3472096

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:21
User entered 'Yes (Y)'		18 Mar 2021 14:41:58

US3472096

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User entered 'I'	System	18 Mar 2021 14:41:58

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:16:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 01:32:30

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:30
User entered '31 Mar 2021'		01 Apr 2021 01:32:30

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:30
User entered 'Contact Made (CONTACT MADE)'		01 Apr 2021 01:32:30

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:30
User entered empty.		01 Apr 2021 01:32:30

US3472096

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:34
User entered 'Yes (Y)'		01 Apr 2021 01:32:36

US3472096

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User entered 'I'	System	01 Apr 2021 01:32:36

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:36:40

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:36:40

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:36:40

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	21 Apr 2021 17:36:40

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '12:12'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User entered '20 Apr 2021 12:12'	System	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '73'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '139'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '83'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:54

US3472096

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:54

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:38:06

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:38:06

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '12:20'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:38:06

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User entered '20 Apr 2021 12:20'	System	21 Apr 2021 17:38:06

US3472096

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:38:12

US3472096

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:38:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (09NOV2020). Please review and reconcile ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:02:50
Query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (09NOV2020). Please review and reconcile ' answered with 'data is accurate' (Site from DM).		06 Jan 2021 14:25:41
User opened query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (09NOV2020). Please review and reconcile ' (Site from DM).		05 Jan 2021 19:43:54
DataPoint Verified.		19 Nov 2020 15:44:54
User closed query 'Re-query: It is to be completed upon learning of positive result. If there is any new information it is to be updated within 24 hrs. Please review training slides sent to sites on 04Sep2020.' (Site from CRA).		17 Nov 2020 02:13:33
Query 'Re-query: It is to be completed upon learning of positive result. If there is any new information it is to be updated within 24 hrs. Please review training slides sent to sites on 04Sep2020.' answered with 'Thanks for your guidance. I personally did not receive a slide deck on 04SEP2020 but I will check with our CRA to see what this refers to. Severity Assessment completed.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 16:38:40
User opened query 'Re-query: It is to be completed upon learning of positive result. If there is any new information it is to be updated within 24 hrs. Please review training slides sent to sites on 04Sep2020.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:34:37
User closed query 'Please reconcile and add severity page as required.' (Site from CRA).		16 Nov 2020 12:34:37

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Please reconcile and add severity page as required.' answered with 'We are in communication with our CRA to determine exactly when the severity assessment needs to be completed as it is unclear to us after review of the protocol and CCGs.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:20:52
User opened query 'Please reconcile and add severity page as required.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:42:07
User entered '09 Nov 2020'		10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:54
User entered '09:45'		10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '09 Nov 2020 09:45'	System	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:44:54
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:54
User entered 'Yes (Y)'		10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:55:19
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User closed query 'Re-query: Per CCGs and training provided to all sites on 04Sep2020 first day of symptom log = first day subject experiences symptoms. Please correct log as previously requested.' (Site from CRA).		17 Nov 2020 02:12:43
Query 'Re-query: Per CCGs and training provided to all sites on 04Sep2020 first day of symptom log = first day subject experiences symptoms. Please correct log as previously requested.' answered with 'Updated the Symptom log to accurately reflect Symptom Day.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 16:55:39
User opened query 'Re-query: Per CCGs and training provided to all sites on 04Sep2020 first day of symptom log = first day subject experiences symptoms. Please correct log as previously requested.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:35:33
User closed query 'Please reconcile log. Symptom Day 1 = first day subject experienced symptoms' (Site from CRA).		16 Nov 2020 12:35:33
Query 'Please reconcile log. Symptom Day 1 = first day subject experienced symptoms' answered with 'Per protocol, Day 1 is the Illness Visit.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 02:54:52
User opened query 'Please reconcile log. Symptom Day 1 = first day subject experienced symptoms' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:42:30
User entered '10 Nov 2020'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.1' F		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	(b) (4)	
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:11
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	16 Nov 2020 16:55:19
		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '98.1' F	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:55:19
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '12 Nov 2020'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '94'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '100.0' F		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '13 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.1' F		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:40:54

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 6 (Day 6)'	Jie Ho (b) (4)	17 Nov 2020 03:16:04
	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '14 Nov 2020'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '100.0' F		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Please add Day 1 to line 7. If not assessed because it was before subject called site it should be recorded with day symptoms started and checked for assessment not done' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:32:49
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
Query 'Please add Day 1 to line 7. If not assessed because it was before subject called site it should be recorded with day symptoms started and checked for assessment not done' answered with 'Updated.' (Site from CRA).	Jie Ho (b) (4)	17 Nov 2020 03:17:13
User opened query 'Please add Day 1 to line 7. If not assessed because it was before subject called site it should be recorded with day symptoms started and checked for assessment not done' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:12:33
User entered '15 Nov 2020'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '97'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '99.0' F	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	(b) (4)	
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 1 (Day 1)'	Jie Ho (b) (4)	17 Nov 2020 03:16:04
	Jie Ho (b) (4)	17 Nov 2020 03:10:02

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '09 Nov 2020'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered missing code ND - Not Done.	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99' F	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '16 Nov 2020'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '95'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.0' F		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		18 Nov 2020 17:16:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '17 Nov 2020'		18 Nov 2020 17:17:41

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		18 Nov 2020 17:17:41

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '98.4' F	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 18Nov2020. Please review data and consider updating to 'Day 10' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM). Query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 18Nov2020. Please review data and consider updating to 'Day 10' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' answered with 'updated' (Site from DM). User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 16:12:22
User opened query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 18Nov2020. Please review data and consider updating to 'Day 10' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM). User entered 'Day 11 (Day 11)'		15 Mar 2021 13:19:53
		15 Mar 2021 13:19:42
		14 Mar 2021 21:54:20
		19 Nov 2020 14:39:17

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered '97'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	19 Nov 2020 14:39:17

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98.9' F		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	9 Nov 2020 15:48:49
User entered 'Mild (Mild)'		9 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error		22 Nov 2020 22:10:18
User entered 'Day 2 (Day 2)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered '19 Nov 2020'		20 Nov 2020 13:19:25

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered '97'		20 Nov 2020 13:19:25

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered '97.2' F		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 13 (Day 13)'		22 Nov 2020 22:10:18

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '20 Nov 2020'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '99'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	22 Nov 2020 22:10:18

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered '98.0' F		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:10:18

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 14 (Day 14)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '21 Nov 2020'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.2' F		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:11:03

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 15 (Day 15)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '22 Nov 2020'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered '0'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered '97.2' F		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 15 (Day 15)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 16 (Day 16)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '23 Nov 2020'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered '0'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '99'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97.5' F		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 16 (Day 16)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 17 (Day 17)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '24 Nov 2020'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered '99'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.2' F		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 18 (Day 18)'		01 Dec 2020 18:15:07

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered '25 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 18:15:07

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered '99'	(b) (4), (b) (6)	01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	01 Dec 2020 18:15:07

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.4' F		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 19 (Day 19)'		01 Dec 2020 18:18:12

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '26 Nov 2020'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '99'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered '98.2' F		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 20 (Day 20)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '27 Nov 2020'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered '0'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered '97.6' F	(b) (4), (b) (6)	01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:20:07
User entered 'Day 21 (Day 21)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered '28 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered '98'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	01 Dec 2020 18:22:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.2' F		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

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Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered '10 Nov 2020'		10 Nov 2020 20:16:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[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 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered 'Yes (Y)'		10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[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 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
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)	17 Nov 2020 14:51:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 14:51:04
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 'AE added to Log.' (Site from System).	Jie Ho (b) (4)	16 Nov 2020 03:25:58
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	12 Nov 2020 22:35:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 22:35:22
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:16:56
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:16:52
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:44:30
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:44:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

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 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:39:33
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:39:23
User entered 'No (N)' reason for change: Data Entry Jie Ho Error	(b) (4)	12 Nov 2020 22:39:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 22:39:23
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:17:10
User entered 'PENDING' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:17:10
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:16:52
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 22:39:33
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:17:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:17:10
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:16:52
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered 'I'	System	12 Nov 2020 22:35:22

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

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 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered '93' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 16:31:40
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:31:40
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
User closed query 'Per ETRTR: Please complete all missing fields on this page. Thanks!' (Site from CRA).		02 Apr 2021 13:39:27
Query 'Per ETRTR: Please complete all missing fields on this page. Thanks!' answered with 'Updated.' (Site from CRA).	Jie Ho (b) (4)	04 Dec 2020 17:13:41
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:07
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:07
User opened query 'Per ETRTR: Please complete all missing fields on this page. Thanks!' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 15:03:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:39:43
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:46:48

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:39:57
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:34
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 16:31:40
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:31:40
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Start Date](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:46:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:51
User entered 'No (N)'	Jie Ho (b) (4)	04 Dec 2020 17:46:16

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '12 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)' reason for change: Data Entry Error		16 Nov 2020 20:38:05
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Per ETRTR: Date of collection for Day 5 is one day after Day 3. Please confirm Date of collection and update if applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:30:21
Query 'Per ETRTR: Date of collection for Day 5 is one day after Day 3. Please confirm Date of collection and update if applicable.' answered with 'This is the correct date. Sample pick up could not be arranged for 11/14/2020 so sample was collected on 11/13/2020.' (Site from CRA).	Jie Ho (b) (4)	03 Dec 2020 19:08:32
User opened query 'Per ETRTR: Date of collection for Day 5 is one day after Day 3. Please confirm Date of collection and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 14:59:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:38:05
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)' reason for change: New Information		19 Nov 2020 14:38:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '16 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 14:38:00
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)' reason for change: New Information		19 Nov 2020 14:38:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '18 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 14:38:00
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:46:48

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:13:21
User entered 'Yes (Y)' reason for change: Data Entry Error		24 Nov 2020 18:13:21
DataPoint Verified.		19 Nov 2020 15:47:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:13:21
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:13:21
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 18:28:06
User entered 'Yes (Y)' reason for change: Data Entry Error		01 Dec 2020 18:28:06
DataPoint Verified.		19 Nov 2020 15:47:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 18:28:06
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:28:06
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:30:29
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 18:03:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 18:03:13
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	03 Dec 2020 18:03:13
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 18:03:07
DataPoint Un-verified.	Jie Ho (b) (4)	03 Dec 2020 18:03:07
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	03 Dec 2020 18:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:38
User closed query 'Please reconcile and add saliva page' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:33:39
Query 'Please reconcile and add saliva page' answered with 'Saliva log updated.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:14:27
User opened query 'Please reconcile and add saliva page' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:41:41
User entered 'Yes (Y)'		10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:46:38
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:38
User entered 'Home (Home)'		10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:46:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '10 Nov 2020'		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '13:15'		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User entered '10 Nov 2020 13:15'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 20:18:11
DataPoint set to visible.	System	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 20:18:11
DataPoint set to visible.	System	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:46:46
User entered '99.1' F	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered 'Oral (Oral)'		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered empty.		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '80'		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:46:46
User entered '17'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:46:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:18:17

US3472096

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:56
User entered '10 Nov 2020'		10 Nov 2020 20:18:17

US3472096

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:46:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:18:24

US3472096

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:03
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:18:24

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:20
User entered 'No (N)'		01 Mar 2021 15:07:53

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:20:20
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:07:53

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:20:20
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:07:53

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	01 Mar 2021 15:07:53

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:20:26
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:20:26
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:20:26
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:20:26
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:20:26
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:20:26
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:20:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 15:08:07

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:20:30
User entered empty.		01 Mar 2021 15:08:07

US3472096

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:46:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 15:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 13:14:59
Query 'Data is required. Please complete.' answered with 'erroneously entered to D28' (Site from System).	Jie Ho (b) (4)	16 Nov 2020 03:18:27
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:18:11
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:18:11
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:17:49

US3472096

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:36
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:18:11
User entered '10 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:17:49

US3472096

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

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:04:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 04:58:40

US3472096

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

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:04:55
User entered '5 Feb 2021'	(b) (4), (b) (6)	06 Feb 2021 04:58:40

US3472096

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

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[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 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:04:55
User entered 'Clinic (Clinic)'		06 Feb 2021 04:58:40

US3472096

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

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'UNBLND_DECIDE'	System	06 Feb 2021 04:58:40

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered '5 Feb 2021'		06 Feb 2021 04:59:27

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:25:44

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered 'Yes (Y)'		06 Feb 2021 04:59:27

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
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 15:25:44

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered '5 Feb 2021'		06 Feb 2021 04:59:27

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered 'Placebo (Placebo)'		06 Feb 2021 04:59:27

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:00
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Feb 2021 04:59:27

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:00
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	06 Feb 2021 04:59:27

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 04:59:27

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '1'	System	06 Feb 2021 04:59:27

US3472096

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

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'I'	System	06 Feb 2021 04:59:27

US3472096

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered empty.	System	06 Feb 2021 05:02:27
DataPoint set to visible.	System	06 Feb 2021 04:59:27

US3472096

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered empty.	System	06 Feb 2021 05:02:27
DataPoint set to visible.	System	06 Feb 2021 04:59:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User accepted default value 'Pre-Dose (PREDOSE)'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered 'Yes (Y)'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '5 Feb 2021'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '11:02'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 11:02'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '36.8' C		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:06
User entered empty.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:06
User entered '74'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'bpm'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:06
User entered '12'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'breaths/min'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:06
User entered '166'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mmHg'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '93'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mmHg'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered empty.	System	06 Feb 2021 05:02:27
DataPoint set to visible.	System	06 Feb 2021 04:59:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered 'Yes (Y)'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '5 Feb 2021'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '14:15'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 14:15'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '36.8' C		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered empty.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '80'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'bpm'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:06
User entered '14'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'breaths/min'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '156'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mmHg'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '86'		06 Feb 2021 05:02:27

US3472096

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mmHg'	System	06 Feb 2021 05:02:27

US3472096

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 05:02:35

US3472096

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:11
User entered '5 Feb 2021'		06 Feb 2021 05:02:35

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 05:03:00

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered empty.		06 Feb 2021 05:03:00

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered empty.		06 Feb 2021 05:03:00

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mRNA-1273'	System	06 Feb 2021 05:03:00
DataPoint set to visible.	System	06 Feb 2021 04:59:27

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered '5 Feb 2021'		06 Feb 2021 05:03:00

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:17
User entered '13:50'	(b) (4), (b) (6)	06 Feb 2021 05:03:00

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 13:50'	System	06 Feb 2021 05:03:00

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered 'Right Arm (RIGHT ARM)'		06 Feb 2021 05:03:00

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
DataPoint Verified.		08 Apr 2021 14:05:17
User entered 'ONCE'	System	06 Feb 2021 05:03:00

US3472096

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

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'INTRAMUSCULAR'	System	06 Feb 2021 05:03:00

US3472096

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:22
User entered 'Yes (Y)'		06 Feb 2021 05:03:16

US3472096

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:22
User entered '5 Feb 2021'		06 Feb 2021 05:03:16

US3472096

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:22
User entered '11:12'		06 Feb 2021 05:03:16

US3472096

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 11:12'	System	06 Feb 2021 05:03:16

US3472096

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User entered 'Yes (Y)'		06 Feb 2021 05:03:33

US3472096

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:05:26
User entered '5 Feb 2021'	(b) (4), (b) (6)	06 Feb 2021 05:03:33

US3472096

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User entered '11:06'		06 Feb 2021 05:03:33

US3472096

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 11:06'	System	06 Feb 2021 05:03:33

US3472096

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

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:32
User entered 'Yes (Y)'		06 Feb 2021 05:03:38

US3472096

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

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'I'	System	06 Feb 2021 05:03:38

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:11:22
User entered 'Yes (Y)'		11 Feb 2021 18:08:18

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:11:22
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 18:22:05
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 18:08:18

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:22
User entered 'Contact Made (CONTACT MADE)'		11 Feb 2021 18:08:18

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:22
User entered empty.		11 Feb 2021 18:08:18

US3472096

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:10:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 18:08:24

US3472096

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User entered 'I'	System	11 Feb 2021 18:08:24

US3472096

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User entered '1'	System	11 Feb 2021 18:08:24
DataPoint set to visible.	System	11 Feb 2021 18:08:24

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:19
User entered 'Yes (Y)'		10 Mar 2021 18:53:57

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:19
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 18:53:57

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[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 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:19
User entered 'Clinic (Clinic)'		10 Mar 2021 18:53:57

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'OLD29'	System	10 Mar 2021 18:53:57

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered 'Yes (Y)'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '9 Mar 2021'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '11:30'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered '9 Mar 2021 11:30'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '36.3' C		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered empty.		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:30
User entered '67'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'bpm'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '16'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'breaths/min'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:30
User entered '144'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mmHg'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '90'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mmHg'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered 'Yes (Y)'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:30
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '13:39'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered '9 Mar 2021 13:39'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '36.6' C		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:30
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '59'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'bpm'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '16'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'breaths/min'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:30
User entered '144'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mmHg'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '85'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mmHg'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 18:56:15

US3472096

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:34
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 18:56:15

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:41
User entered 'Yes (Y)'		10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:41
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:41
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mRNA-1273'	System	10 Mar 2021 18:56:39
DataPoint set to visible.	System	11 Feb 2021 18:08:24

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:41
User entered '9 Mar 2021'		10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:41
User entered '13:09'	(b) (4), (b) (6)	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered '9 Mar 2021 13:09'	System	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:41
User entered 'Right Arm (RIGHT ARM)'		10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
DataPoint Verified.		08 Apr 2021 14:12:41
User entered 'ONCE'	System	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:46
User entered 'Yes (Y)'		10 Mar 2021 18:57:00

US3472096

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'I'	System	10 Mar 2021 18:57:00

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 23:51:28

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:54
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 23:51:28

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:54
User entered 'Contact Made (CONTACT MADE)'		17 Mar 2021 23:51:28

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:54
User entered empty.		17 Mar 2021 23:51:28

US3472096

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:12:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 23:51:40

US3472096

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User entered 'I'	System	17 Mar 2021 23:51:40

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:49:51

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:49:51

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:49:51

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	20 Apr 2021 22:49:51

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '12:12'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User entered '20 Apr 2021 12:12'	System	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '73'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '139'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '83'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:58

US3472096

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:58

US3472096

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:51:11

US3472096

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:51:11

US3472096

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '12:20'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:51:11

US3472096

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User entered '20 Apr 2021 12:20'	System	20 Apr 2021 22:51:11

US3472096

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:46:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:36:56
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 06:08:29
Query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'This has a corresponding AE - elevated blood pressure, which is already in the AE log in the EDC.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:32:02
User opened query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:09:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:36
User closed query 'Please reconcile and add COVID 19 as central lab provided positive illness results' (Site from CRA).		16 Nov 2020 12:37:06

US3472096

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:46:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Please reconcile and add COVID 19 as central lab provided positive illness results' answered with 'Updated AE log.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:32:25
User opened query 'Please reconcile and add COVID 19 as central lab provided positive illness results' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:41:27
User entered 'Yes (Y)'		10 Nov 2020 20:18:46

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:53:58
User entered 'USA-US122-2020-mRNA-1273-P301000003'	System	16 Nov 2020 19:53:36
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 19:53:36

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
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)	16 Nov 2020 03:26:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:26:02
Data point term sent to Coder	System	16 Nov 2020 03:25:09
User entered 'COVID-19'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'PV Query: The start date of the event is 09 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 09 Nov 2020 to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:40:14
Query 'PV Query: The start date of the event is 09 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 09 Nov 2020 to the COVID-19 assessment symptom log in EDC.' answered with '09Nov2020 is on the symptom log..please clarify.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:21:34
User opened query 'PV Query: The start date of the event is 09 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 09 Nov 2020 to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:46:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '09 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:28:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:28:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:28:39
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:28:39
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:40:11
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'This is marked ongoing..please clarify query.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:22:14
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:45:48
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' answered with 'Updated.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:40:07
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:27:23
User entered 'Not Related (NOT RELATED)'	Jie Ho (b) (4)	23 Nov 2020 04:27:15
reason for change: Data Entry Error		
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:46:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Related (RELATED)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Not Related (NOT RELATED)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:40:05
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 15:33:15
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Reason was changed to "Due to SARSCOV2.' (Site from System).	Jie Ho (b) (4)	23 Nov 2020 04:29:46
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'Updated.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:28:02
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Nov 2020 04:27:41
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Not Applicable (NOT APPLICABLE)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'I'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:28:39
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:40:02
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'we will respond when his symptoms resolve.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 15:35:32
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:28:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:28:34
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:46:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:59:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:59:55
Data point term sent to Coder	System	10 Mar 2021 18:59:41
User entered 'Elevated blood pressure'	(b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 20:14:08
User entered '12:00' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 20:14:08
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Mar 2021 18:59:24
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Feb 2021 12:00'	System	15 Mar 2021 20:14:08
User entered empty.	System	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Mar 2021 19:00:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:00:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:00:45
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 18:59:24
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Mar 2021 19:00:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:00:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:00:45
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 18:59:24
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Mar 2021 19:00:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:00:45
User entered 'None (NONE)' reason for change:	(b) (4), (b) (6)	10 Mar 2021 19:00:45
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 18:59:24
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Participant has scheduled an appointment with a cardiologist for March 25th, 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 18:59:24

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 18:59:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:46:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:53:45
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:48
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
Un-reviewed for Data Management.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 08:13:14
Reviewed for Data Management.	(b) (4), (b) (6)	01 Feb 2021 08:13:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 17:27:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 17:27:14
Data point term sent to Coder	System	10 Dec 2020 17:25:38
Coding entries removed.	Jie Ho (b) (4)	10 Dec 2020 17:24:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Dec 2020 01:00:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Dec 2020 01:00:05
Data point term sent to Coder	System	06 Dec 2020 00:58:49
Coding entries removed.	(b) (4), (b) (6)	06 Dec 2020 00:58:09
DataPoint Verified.		19 Nov 2020 15:47:58

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:39:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:39:24
Data point term sent to Coder	System	07 Oct 2020 18:49:18
User entered 'ibuprofen'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
User closed 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).		01 Feb 2021 09:23:41
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. ' answered with 'Reported conmed ibuprofen is not taken for any diagnosed condition. It is taken prn as noted for isolated events of generalized pain and indication was determined by PI not to be reportable as per protocol' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:18:49
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)	22 Jan 2021 05:16:36
User closed query 'Per CDM re-query: Per previous query, please update the Indication to record what this medication is being taken as prophylactic for and review and reconcile response to 'Prophylaxis' as it is currently NO.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 14:01:46
Query 'Per CDM re-query: Per previous query, please update the Indication to record what this medication is being taken as prophylactic for and review and reconcile response to 'Prophylaxis' as it is currently NO.' answered with 'This was incorrectly updated.' (Site from DM).	Jie Ho (b) (4)	10 Dec 2020 17:25:01
User entered 'Generalized Pain' reason for change: Per Query Resolution	Jie Ho (b) (4)	10 Dec 2020 17:24:49

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Per previous query, please update the Indication to record what this medication is being taken as prophylactic for and review and reconcile response to 'Prophylaxis' as it is currently NO.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:01:55
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	09 Dec 2020 16:01:55
' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	06 Dec 2020 00:58:09
User entered 'prophylactic' reason for change: Data Entry Error		06 Dec 2020 00:58:09
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.		06 Dec 2020 00:57:54
' answered with 'prophylactic' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	27 Nov 2020 08:50:19
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed pain relief'	Petra Alexander (b) (4)	07 Oct 2020 18:49:11
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '400'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed (PRN)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2000'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CARBAMAZEPINE, PRODUCTSYNONYM: TEGRETOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 21:45:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 21:45:59
	(b) (4)	
Data point term sent to Coder	System	07 Oct 2020 18:50:20
User entered 'tegretol'	Petra Alexander (b) (4)	07 Oct 2020 18:49:56
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'BPD'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '400'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2000'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:28:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:28:50
Data point term sent to Coder	System	07 Oct 2020 19:42:21
User entered 'zoloft'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'BPD'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '200'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '01 Sep 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE, PRODUCTSYNONYM: DYMISTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 07:54:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 07:54:07
Data point term sent to Coder	System	06 Dec 2020 01:42:53
Coding entries removed.	(b) (4), (b) (6)	06 Dec 2020 01:42:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE, PRODUCTSYNONYM: DYMISTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Oct 2020 14:54:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Oct 2020 14:54:20
Data point term sent to Coder	System	07 Oct 2020 19:43:25
User entered 'Dymista nasal spray'	Petra Alexander (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Allergic rhinitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '2'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'sprays'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate. ' (Site from DM).		09 Dec 2020 16:02:13
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate. ' answered with 'Nasal' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 01:42:52
DataPoint Un-verified.	(b) (4), (b) (6)	06 Dec 2020 01:42:36
User entered 'Nasal (NASAL)' reason for change: Data Entry Error		06 Dec 2020 01:42:36
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate. ' (Site from DM).		27 Nov 2020 08:51:07
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2000'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: VARIOUS, ATC: ALLERGENS, ATC: ALLERGENS, ATC: ALLERGEN EXTRACTS, PRODUCT: ALLERGENS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:44
Data point term sent to Coder	System	07 Oct 2020 19:44:28
User entered 'Allergy shots'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'allergic rhinitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'I'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Injection'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'every month (QM)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Subcutaneous (SUBCUTANEOUS)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2016'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:01:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:01:22
Data point term sent to Coder	System	07 Oct 2020 19:45:33
User entered 'ketoconazole cream'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Seborrheic dermatitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'I'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Application'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed (PRN)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Topical (TOPICAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2017'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 16:54:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 16:54:25
Data point term sent to Coder	System	04 Nov 2020 16:38:57
Data point term sent to Coder	System	04 Nov 2020 16:28:42
User entered 'Influenza vaccination'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Influenza prophylaxis'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '0.5'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mL (mL)'		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 16:38:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 16:38:24
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 16:38:24
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 16:27:48
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '21 Oct 2020'		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '21 Oct 2020'		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:18:32
Data point term sent to Coder	System	12 Nov 2020 16:18:13
User entered 'Vitamin D3'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'		12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Supplement'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '5000'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'IU (IU)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'		12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:18:32
Data point term sent to Coder	System	12 Nov 2020 16:18:13
User entered 'Vitamin C'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Supplement'		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '1000'		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '10 Nov 2020'		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:55:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:55:39
Data point term sent to Coder	System	12 Nov 2020 16:18:13
User entered 'Zinc lozenges'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Supplement'		12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'UNK'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'		12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'		12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'		12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 23:03:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 23:03:36
Data point term sent to Coder	System	12 Nov 2020 23:03:09
User entered 'Azithromycin'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'		12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'COVID-19'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '500'		12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'		12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 23:12:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 23:12:41
Data point term sent to Coder	System	12 Nov 2020 23:04:10
User entered 'Albuterol'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'COVID-19'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '180'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:30:20
User entered 'ug (ug)' reason for change: Data Entry	Jie Ho (b) (4)	23 Nov 2020 04:30:20
Error		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User closed query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).		23 Nov 2020 15:33:35
Query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	23 Nov 2020 04:30:28
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:30:20
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:30:20
User opened query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:53:18
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mcg'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 18:29:26
User entered 'No (N)' reason for change: Data Entry Error		01 Dec 2020 18:29:26
DataPoint Verified.		19 Nov 2020 15:47:58
User entered 'Yes (Y)'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 18:29:26
User entered '29 Nov 2020' reason for change: Data Entry Error		01 Dec 2020 18:29:26
DataPoint Verified.		19 Nov 2020 15:47:58
User entered empty.		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
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 18:12:55
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 18:12:55
Data point term sent to Coder	System	11 Feb 2021 18:12:29
User entered 'Acetaminophen'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'No (N)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:22:16
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).		03 Mar 2021 13:57:27
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.	(b) (4), (b) (6)	02 Mar 2021 18:45:31
' answered with 'Per protocol, indication not reportable as AE for part B' (Site from DM).		
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)	02 Mar 2021 08:38:38
User entered 'Pain at injection site'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered '650'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'mg (mg)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'once (ONCE)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'Oral (ORAL)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered '6 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered '0'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'No (N)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered '6 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. Otherwise, provide clarification. ' (Site from DM).		03 Mar 2021 13:57:33
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	02 Mar 2021 18:45:40
' answered with 'updated' (Site from DM).		
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 18:45:36
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. Otherwise, provide clarification. ' (Site from DM).		02 Mar 2021 08:38:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 16:21:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 16:21:46
Data point term sent to Coder	System	22 Mar 2021 16:20:16
User entered 'Lisinopril'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered 'Elevated blood pressure'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered '20'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'once daily (QD)'		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'Oral (ORAL)'		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered '18 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'Yes (Y)'		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'No (N)'		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:46:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:13:47
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:41:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:41:20
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:41:20
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:41:07
User entered empty; reason for change Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:41:07
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:40:42

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:46:48

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:50:42
User entered '09 Nov 2020'	Jie Ho (b) (4)	23 Nov 2020 04:27:41

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:46:48

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query ' Per CDM: Reason for dose not given is 'Other' with specification "PARTICIPANT NEEDED TO LEAVE FOR ANOTHER APPOINTMENT." under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Due to SARS-COV-2'. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' (Site from DM). Query ' Per CDM: Reason for dose not given is 'Other' with specification "PARTICIPANT NEEDED TO LEAVE FOR ANOTHER APPOINTMENT." under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Due to SARS-COV-2'. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' answered with 'Both are accurate - dose was not given at that visit because participant had to leave for another appt - visit was rescheduled for a few days later, but in that interim ppt reported covid symptoms and tested positive, so could not be dosed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:20
User opened query ' Per CDM: Reason for dose not given is 'Other' with specification "PARTICIPANT NEEDED TO LEAVE FOR ANOTHER APPOINTMENT." under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Due to SARS-COV-2'. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' answered with 'Both are accurate - dose was not given at that visit because participant had to leave for another appt - visit was rescheduled for a few days later, but in that interim ppt reported covid symptoms and tested positive, so could not be dosed.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:29:37
User opened query ' Per CDM: Reason for dose not given is 'Other' with specification "PARTICIPANT NEEDED TO LEAVE FOR ANOTHER APPOINTMENT." under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Due to SARS-COV-2'. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:58:11
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 23:50:42
User entered 'Due to SARS-COV-2 (COVID)'	Jie Ho (b) (4)	23 Nov 2020 04:27:41

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:46:48

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:50:42
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:27:41

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
Reviewed for Safety.	(b) (4)	30 Nov 2020 21:40:25
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
User entered 'US'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 13:56:59
User entered '2'	System	30 Nov 2020 21:40:50
User entered '1'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Death

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
Reviewed for Safety.	(b) (4)	30 Nov 2020 21:40:25
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
User entered 'US'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 13:56:59
User entered '2'	System	30 Nov 2020 21:40:50
User entered '1'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:46:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:43
User entered '16/Nov/2020 14:54'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:46:48

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.	Ian Frank (b) (4)	02 May 2021 19:11:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:40:25
DataPoint Verified.		19 Nov 2020 15:39:43
User entered 'I'		16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Death

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
Reviewed for Safety.	(b) (4)	30 Nov 2020 21:40:25
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
User entered 'US'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 13:56:59
User entered '2'	System	30 Nov 2020 21:40:50
User entered '1'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:46:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:51
User entered '30/Nov/2020 21:40'	System	30 Nov 2020 21:40:50

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:46:48

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.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	08 Apr 2021 14:23:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:56:44
User entered 'I'		30 Nov 2020 21:40:50

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

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Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

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[Investigator Country](#)

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User entered 'US'	System	16 Nov 2020 19:54:17

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Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 13:56:59
User entered '2'	System	30 Nov 2020 21:40:50
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US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:51
User entered '01/Dec/2020 13:56'	System	01 Dec 2020 13:56:59

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

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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)
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:51
User entered 'I'		01 Dec 2020 13:56:59