

US3472130 (Prod: Penn Prevention - (CRS))

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:48:19

All time stamps listed in this document are displayed in GMT

US3472130

Form: Participant Creation

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

[Participant ID](#)

US3472130

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

US3472130

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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 19:16:23

Generated On: 11 Aug 2021 22:48:19

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	46
Age Units	YEARS
Age (Derived)	46
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	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	23 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 19:16:23

Generated On: 11 Aug 2021 22:48:19

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 19:16:23

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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 19:16:23

Generated On: 11 Aug 2021 22:48:19

Condition	MITRAL VALVE PROLAPSE
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Start Year (derived)	1983
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 19:16:23

Generated On: 11 Aug 2021 22:48:19

Condition	BICUSPID AORTIC VALVE SYNDROME
Start date (dd MMM yyyy)	(b) (6) 1973
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)	(b) (6) 1973
Start Year (derived)	1973
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Condition	SCIATICA
Start date (dd MMM yyyy)	UN MAY 2013
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)	MAY 2013
Start Year (derived)	2013
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 19:16:23

Generated On: 11 Aug 2021 22:48:19

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN SEP 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2012
Start Year (derived)	2012
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 19:16:23

Generated On: 11 Aug 2021 22:48:19

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN JUN 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)	JUN 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 19:16:23

Generated On: 11 Aug 2021 22:48:19

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Condition	OBESITY, CLASS II
Start date (dd MMM yyyy)	UN OCT 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)	OCT 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3472130

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 11:25
Height (xxx.x)	188 cm
Weight (xxx.x)	124.7 kg
BMI (xxx.x)	35.28180 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 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 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 19:16:23

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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

(b) (6) FOR
FEDERAL AGENCY

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 19:16:23

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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 16:05:50

Generated On: 11 Aug 2021 22:48:19

What was the date of randomization? (dd MMM yyyy) 23 OCT 2020

What was the participant's randomization number? 147311

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 16:05:50

Generated On: 11 Aug 2021 22:48:19

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 16:05:50

Generated On: 11 Aug 2021 22:48:19

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)	23 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 11:25
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 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 16:05:50

Generated On: 11 Aug 2021 22:48:19

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)	23 OCT 2020
Time of assessment (00:00-23:59)	13:31 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 13:31
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 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 16:05:50

Generated On: 11 Aug 2021 22:48:19

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 16:05:50

Generated On: 11 Aug 2021 22:48:19

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) 23 OCT 2020

What was the treatment time? (00:00-23:59) 12:56 (24 HR)

Treatment Date and Time (derived) 23 OCT 2020 12:56

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 16:05:50

Generated On: 11 Aug 2021 22:48:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	12:45 (24 HR)
Collection date and time (derived)	23 OCT 2020 12:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Collection date (dd MMM yyyy)			23 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:37	23 OCT 2020 12:37
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

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 22:48:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 13:29

PC Open Date & Time

23 OCT 2020 13:16

PC Close Date & Time

23 OCT 2020 15:46

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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 98.0 °F

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

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

PC Time Stamp	23 OCT 2020 23:38
PC Open Date & Time	23 OCT 2020 16:41
PC Close Date & Time	24 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:48:19

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

97.4 °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

24 OCT 2020 20:58

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 13:07

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 12:02

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:48:19

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 12:15

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

28 OCT 2020 15:41

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:48:19

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

98.3 °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

29 OCT 2020 12:24

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

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

23 OCT 2020 13:21

PC Open Date & Time

23 OCT 2020 13:16

PC Close Date & Time

23 OCT 2020 15:46

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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 ☐

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

2

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

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

Yes ☐

No ☒

Please record - **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

23 OCT 2020 23:41

PC Open Date & Time

23 OCT 2020 16:41

PC Close Date & Time

24 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

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 ☐

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

2

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

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

Yes ☐

No ☒

Please record - **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

24 OCT 2020 20:58

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 3

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 ☐

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

2

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

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

Yes ☐

No ☒

Please record - **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

25 OCT 2020 13:07

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

2

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

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

Yes ☐

No ☒

Please record - **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

26 OCT 2020 12:00

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

2

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

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

Yes ☐

No ☒

Please record - **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

27 OCT 2020 12:16

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

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 ☐

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

1

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

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

Yes ☐

No ☒

Please record - **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

28 OCT 2020 15:41

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm)	1
Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	29 OCT 2020 12:23
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 13:22
PC Open Date & Time	23 OCT 2020 13:16
PC Close Date & Time	23 OCT 2020 15:46

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 23:42
PC Open Date & Time	23 OCT 2020 16:41
PC Close Date & Time	24 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

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 ☒

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 20:58
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

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 ☒

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 13:08
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 12:00
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

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 ☒

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 12:16
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

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 ☒

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 15:42
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 12:23
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

1

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

PC Time Stamp 30 OCT 2020 23:59

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 9

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

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

PC Time Stamp

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 10

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

1

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

PC Time Stamp

01 NOV 2020 15:25

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 11

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

1

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

PC Time Stamp 03 NOV 2020 00:52

PC Open Date & Time 02 NOV 2020 12:00

PC Close Date & Time 03 NOV 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 12

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☒

PC Time Stamp

03 NOV 2020 12:08

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:48:19

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	30 OCT 2020 23:59
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:48:19

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	01 NOV 2020 15:25
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT	DAY 11
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	03 NOV 2020 00:52
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 12

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

No ☒

Yes ☐

PC Time stamp

03 NOV 2020 12:08

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3472130

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472130

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

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 VISIT2

US3472130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3472130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
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	

US3472130

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

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.

US3472130

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

Was study treatment given?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
If No, reason not given	Participant declined due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Physician withheld dose due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-Up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated by Sponsor <input type="checkbox"/>
	Withdrawal of Consent by <input type="checkbox"/>
	Participant <input type="checkbox"/>
	Confirmed COVID-19 <input type="checkbox"/>
	Other <input type="checkbox"/>
<hr/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____	
<hr/>	
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 <input type="checkbox"/>
	Right Arm <input type="checkbox"/>
<hr/>	
What was the frequency of the study treatment dosing?	_____
What was the route of administration for the study treatment?	_____

US3472130

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3472130

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:48:19

Collection date (<i>dd MMM yyyy</i>)			
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3472130

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	14:35 (24 HR)
Vital Signs Date and Time (derived)	21 DEC 2020 14:35
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	95 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3472130

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

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.

US3472130

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 DEC 2020

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

21 DEC 2020 14:40

US3472130

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	27 DEC 2020 00:01
--	-------------------

Patient Cloud Close Date & Time	31 DEC 2020 23:59
---	-------------------

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

17 JAN 2021 02:19:19

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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	24 JAN 2021 02:08:41
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

31 JAN 2021 11:15:22

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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	09 FEB 2021 12:50:34
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

14 FEB 2021 00:33:53

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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	21 FEB 2021 01:17:53
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 06:07:33

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 10:08:58

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 00:29:38

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

21 MAR 2021 00:02:21

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

28 MAR 2021 02:24:24

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 00:04:43

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

11 APR 2021 00:27:28

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

18 APR 2021 11:55:44

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

25 APR 2021 02:42:51

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 208

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 215

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 229

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

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

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

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

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

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

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 516

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

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

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

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

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

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

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

20 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2022 00:01
Patient Cloud Close Date & Time	15 DEC 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

[Patient Cloud Close Date & Time](#)

22 DEC 2022 23:59

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2022 23:59

US3472130

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:48:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 06:07:41

US3472130

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472130

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:05:50

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472130

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472130

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

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 _____

US3472130

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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)	

US3472130

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

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.

US3472130

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3472130

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Date of Contact	06 NOV 2020
Time of Contact	14:20
Date and Time of Contact (derived)	06 NOV 2020 14:20
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>

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	98 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	97 %	
O2 Saturation Units	%	
Temperature	101.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Symptom Day

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	96 %	
O2 Saturation Units	%	
Temperature	100.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Symptom Day

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	93 %	
O2 Saturation Units	%	
Temperature	100.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 06 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Symptom Day

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	93 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 06 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Symptom Day

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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 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 06 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 06 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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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 (7)

Data signed: (b) (4) 02 May 2021 19:16:21

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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 (8)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 (8)

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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	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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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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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 06 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 (9)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	03 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Form: Symptom Log (9)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	04 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Form: Symptom Log (11)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Symptom Day

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

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Form: Symptom Log (11)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	05 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Form: Symptom Log (12)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 02 May 2021 19:16:21

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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	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

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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 06 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 May 2021 19:16:21

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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 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 (13)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	07 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Form: Symptom Log (13)

Data signed: (b) (4) 02 May 2021 19:16:21

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Symptom Day

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	08 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Data signed: (b) (4) 02 May 2021 19:16:21

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 May 2021 19:16:21

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

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Form: Symptom Log (15)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 (15)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 19:16:21

Generated On: 11 Aug 2021 22:48:19

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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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	99 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 06 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		373 of 2452
EAB) (1725)		

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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"/>

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 06 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	98 %	
O2 Saturation Units	%	
Temperature	98.5 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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EAB) (1725)

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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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US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	96.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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 06 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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"/>

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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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US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Date of Visit	09 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	09 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 12 NOV 2020

End Date 14 NOV 2020

Oxygen Saturation 93 %

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 _____

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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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EAB) (1725)

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US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 NOV 2020
Day 5	Yes	13 NOV 2020
Day 7	Yes	16 NOV 2020
Day 9	Yes	17 NOV 2020
Day 14	Yes	23 NOV 2020
Day 21	Yes	30 NOV 2020
Day 28	Yes	07 DEC 2020

US3472130

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 NOV 2020
Time of assessment (00:00-23:59)	12:02 (24 HR)
Vital Signs Date and Time (derived)	09 NOV 2020 12:02
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 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)	

US3472130

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 NOV 2020

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

US3472130

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 19:16:22

Generated On: 11 Aug 2021 22:48:19

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 NOV 2020

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 DEC 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	07 DEC 2020 14:21
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 DEC 2020

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

US3472130

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 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 DEC 2020

US3472130

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

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

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

Visit date (dd MMM yyyy)	03 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3472130

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

Form: Unblinding

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Date of updated informed consent (<i>dd MMM yyyy</i>)	03 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>)	03 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 checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3472130

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

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

US3472130

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

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)	03 FEB 2021
Time of assessment (00:00-23:59)	13:21 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 13:21
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3472130

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

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)	03 FEB 2021
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 14:14
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3472130

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

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 FEB 2021

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

US3472130

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

Form: Exposure

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

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) 03 FEB 2021

What was the treatment time? (00:00-23:59) 13:48 (24 HR)

Treatment Date and Time (derived) 03 FEB 2021 13:48

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

US3472130

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 FEB 2021

Collection time (00:00-23:59)

13:32 (24 HR)

Collection date and time (derived)

03 FEB 2021 13:32

US3472130

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 FEB 2021
Collection time (00:00 - 23:59)	13:34
Collection Date and Time (derived)	03 FEB 2021 13:34

US3472130

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

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472130

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 MAR 2021
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 13:37
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)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 MAR 2021
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 14:14
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3472130

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 MAR 2021

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

US3472130

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 4 MAR 2021

What was the treatment time? (00:00-23:59) 13:44 (24 HR)

Treatment Date and Time (derived) 4 MAR 2021 13:44

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

US3472130

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472130

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472130

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 APR 2021
Time of assessment (<i>00:00-23:59</i>)	15:18 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 15:18
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3472130

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

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.

US3472130

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 APR 2021

Collection time (00:00-23:59)

15:30 (24 HR)

Collection date and time (derived)

5 APR 2021 15:30

US3472130

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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 (9)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

AEID	USA-US122-2020-MRNA-1273-P30 1000002
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)	03 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)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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)	

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

AEID	
Adverse event	INJECTION SITE REDNESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	23 OCT 2020
Start time (00:00-23:59)	23:41 (24 HR)
AE start date and time (derived)	23 OCT 2020 23:41
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 NOV 2020
End time (00:00-23:59)	12:00 (24 HR)
AE End Date and Time (derived)	03 NOV 2020 12:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

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

Yes ☒

No ☐

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

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication SCIATICA

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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 MAY 2013	
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 (2)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Name of Medication BUPROPION

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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 OCT 2019	
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"/>

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Name of Medication ZOLPIDEM TARTRATE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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 OCT 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"/>

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Name of Medication TADALAFIL

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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 JUN 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 (5)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR INFLUENZA

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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)		05 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)		05 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 (6)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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)	03 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)	04 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Name of Medication SUDAFED (325 MG
ACETAMINOPHEN/5MG
PHENYLEPHRINE HCL)

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 2

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	3 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)		17 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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)		04 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)		17 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"/>

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

	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)	06 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)		17 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"/>

US3472130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3472130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 May 2021 19:16:21

Generated On: 11 Aug 2021 22:48:19

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 FEB 2021	ENDOSCOPY	Diagnostic	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 May 2021 19:16:22

Generated On: 11 Aug 2021 22:48:19

Date of dosing discontinuation (dd MMM yyyy) 03 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

US3472130

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:48:19

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 ☐

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

SAEID	USA-US122-2020-MRNA-1273-P301000002
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

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Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

SAEID	USA-US122-2020-MRNA-1273-P301000002
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 09:00
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

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

SAEID	USA-US122-2020-MRNA-1273-P301000002
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 21:22
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

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 02 May 2021 19:16:23

Generated On: 11 Aug 2021 22:48:19

SAEID	USA-US122-2020-MRNA-1273-P301000002
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)	02/DEC/2020 19:16
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

US3472130 (Prod: Penn Prevention - (CRS))

US3472130

Form: Participant Creation

Generated On: 11 Aug 2021 22:48:19

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'US3472130'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:08:35

US3472130

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:17:18

US3472130

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '23 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:08:36

US3472130

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:17:18

US3472130

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'SCRN'	System	23 Oct 2020 17:17:18

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Sex (male) and DOB (1973) recorded on this form. However, Sex and DOB are missing in PPD Central lab. Please reconcile the data and update as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:55:37
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for an Unscheduled Visit, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1973. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 05:41:08
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for an Unscheduled Visit, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1973. Please clarify the subject's Year of Birth and update as appropriate.' answered with 'Data is correct as entered.' (Site from DM).	Jie Ho (b) (4)	02 Nov 2020 20:09:06
Query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Sex (male) and DOB (1973) recorded on this form. However, Sex and DOB are missing in PPD Central lab. Please reconcile the data and update as appropriate' answered with 'Data is correct as entered.' (Site from DM).	Jie Ho (b) (4)	02 Nov 2020 20:09:04
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for an Unscheduled Visit, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1973. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 19:00:32
User opened query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Sex (male) and DOB (1973) recorded on this form. However, Sex and DOB are missing in PPD Central lab. Please reconcile the data and update as appropriate' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:52:22
User entered (b) (6) 1973'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:08:38

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '46'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'YEARS'	System	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '46'	System	23 Oct 2020 17:17:45

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for an Unscheduled Visit has no data recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 05:41:24
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for an Unscheduled Visit has no data recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate. ' answered with 'Data is correct as entered.' (Site from DM).	Jie Ho (b) (4)	02 Nov 2020 20:09:09
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for an Unscheduled Visit has no data recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 21:56:05
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 21:55:43
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 21:55:21
User entered 'Male (M)'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'I'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:48:19

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:54:58

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:17:45

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'Oct 2020'	System	23 Oct 2020 17:17:45

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '2020'	System	23 Oct 2020 17:17:45

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Amendment 4 (4)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:17:45

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:17:45

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:17:45

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:17:45

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:17:45

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:08:36

US3472130

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:48:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'I'	System	23 Oct 2020 17:17:50

US3472130

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:17:50

US3472130

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:48:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:57:41

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve prolapse, LLT: Mitral valve prolapse - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 01:59:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 01:59:30
Data point term sent to Coder	System	27 Oct 2020 01:58:41
User entered 'mitral valve prolapse'	Jie Ho (b) (4)	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un UNK 1983'	Jie Ho (b) (4)	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'Jan 1983'	System	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '1983'	System	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:58:00

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Cardiac valve disorders congenital, PT: Bicuspid aortic valve, LLT: Bicuspid aortic valve - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 06:01:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 06:01:39
Data point term sent to Coder	System	27 Oct 2020 01:58:43
User entered 'Bicuspid Aortic Valve Syndrome'	Jie Ho (b) (4)	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered (b) (6) 1973'	Jie Ho (b) (4)	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered (b) (6) 1973'	System	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '1973'	System	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:58:22

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as SOC: Psychiatric disorders, HLT: Depressive disorders, PT: Major depression, LLT: Major depressive disorder - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:28
Data point term sent to Coder	System	27 Oct 2020 01:59:44
User entered 'Major depressive disorder'	Jie Ho (b) (4)	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un Sep 2019'	Jie Ho (b) (4)	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'Sep 2019'	System	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '2019'	System	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:58:44

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:29
Data point term sent to Coder	System	27 Oct 2020 01:59:45
User entered 'Sciatica'	Jie Ho (b) (4)	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un May 2013'	Jie Ho (b) (4)	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'May 2013'	System	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '2013'	System	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:58:56

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:29
Data point term sent to Coder	System	27 Oct 2020 01:59:44
User entered 'Sleep Apnea'	Jie Ho (b) (4)	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un Sep 2012'	Jie Ho (b) (4)	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'Sep 2012'	System	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '2012'	System	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:59:07

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:28
Data point term sent to Coder	System	27 Oct 2020 01:59:44
User entered 'Erectile Dysfunction'	Jie Ho (b) (4)	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un Jun 2020'	Jie Ho (b) (4)	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'Jun 2020'	System	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '2020'	System	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:59:16

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 02:00:29
Data point term sent to Coder	System	27 Oct 2020 01:59:45
User entered 'insomnia'	Jie Ho (b) (4)	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un Jun 2020'	Jie Ho (b) (4)	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'Jun 2020'	System	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '2020'	System	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:59:26

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
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)	27 Oct 2020 05:25:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 05:25:36
Data point term sent to Coder	System	27 Oct 2020 01:59:46
User entered 'Obesity, class II'	Jie Ho (b) (4)	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un Oct 2020'	Jie Ho (b) (4)	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'Oct 2020'	System	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '2020'	System	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered empty.	System	27 Oct 2020 01:59:39

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '23 Oct 2020'	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '11:25'	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '23 Oct 2020 11:25'	System	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '188' cm	(b) (4)	27 Oct 2020 01:55:35
DataPoint set to visible.	Jie Ho (b) (4)	23 Oct 2020 17:17:50
	System	

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '124.7' kg reason for change: Data Entry Error	(b) (4)	
	Jie Ho (b) (4)	10 Nov 2020 20:55:44
User entered '35.31' kg	Jie Ho (b) (4)	27 Oct 2020 01:55:35
DataPoint set to visible.	System	23 Oct 2020 17:17:50

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered '35.28180'	System	10 Nov 2020 20:55:44
User entered '9.99038'	System	27 Oct 2020 01:55:35
DataPoint set to visible.	System	23 Oct 2020 17:17:50

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'kg/m2'	System	27 Oct 2020 01:55:35
DataPoint set to visible.	System	23 Oct 2020 17:17:50

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'bpm'	System	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'breaths/min'	System	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'mmHg'	System	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User entered 'mmHg'	System	27 Oct 2020 01:55:35

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32

US3472130

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32

US3472130

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 02:03:37

US3472130

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '23 Oct 2020'	Jie Ho (b) (4)	27 Oct 2020 02:03:37

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

[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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

[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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

[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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

[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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered (b) (6) for federal agency'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'I'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

[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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:48:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:32:32
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:56:18

US3472130

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:19:13

US3472130

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:19:13

US3472130

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[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 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:19:13

US3472130

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'VISIT1'	System	23 Oct 2020 17:19:13

US3472130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '23 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:43:32

US3472130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '147311'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:43:32

US3472130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:43:32

US3472130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:48:19

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 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 02:03:09

US3472130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:48:19

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 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 02:03:09

US3472130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:48:19

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 02:03:09

US3472130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:48:19

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 02:03:09

US3472130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:48:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 02:03:09

US3472130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	(b) (4)	27 Oct 2020 02:03:09
DataPoint set to visible.	Jie Ho (b) (4)	23 Oct 2020 17:17:45
	System	

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User accepted default value 'Pre-Dose (PREDOSE)'	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:53:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '23 Oct 2020'	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '11:25'	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered '23 Oct 2020 11:25'	System	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '36.4' C	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Oral (Oral)'	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '77'	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'bpm'	System	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '16'	Jie Ho (b) (4)	27 Oct 2020 01:53:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'breaths/min'	System	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '128'	Jie Ho (b) (4)	27 Oct 2020 01:53:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'mmHg'	System	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '72'	Jie Ho (b) (4)	27 Oct 2020 01:53:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'mmHg'	System	27 Oct 2020 01:53:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered missing code ND - Not Done.	Jie Ho (b) (4)	27 Oct 2020 01:53:19

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User accepted default value 'Post-Dose (POSTDOSE)'	Jie Ho (b) (4)	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '23 Oct 2020'	Jie Ho (b) (4)	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '13:31'	Jie Ho (b) (4)	27 Oct 2020 01:54:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered '23 Oct 2020 13:31'	System	27 Oct 2020 01:54:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '36.5' C	Jie Ho (b) (4)	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Oral (Oral)'	Jie Ho (b) (4)	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:54:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '77'	Jie Ho (b) (4)	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'bpm'	System	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '16'	Jie Ho (b) (4)	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'breaths/min'	System	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '131'	Jie Ho (b) (4)	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'mmHg'	System	27 Oct 2020 01:54:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '78'	Jie Ho (b) (4)	27 Oct 2020 01:54:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'mmHg'	System	27 Oct 2020 01:54:20

US3472130

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 02:03:27

US3472130

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 02:03:27

US3472130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Exposure

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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 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'MRNA-1273 OR PLACEBO'	System	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '12:56'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered '23 Oct 2020 12:56'	System	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'ONCE'	System	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'INTRAMUSCULAR'	System	23 Oct 2020 17:18:53

US3472130

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:53:31

US3472130

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User closed query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 23-OCT-2020. However, this date matches V1D1 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' (Site from DM). Query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 23-OCT-2020. However, this date matches V1D1 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' answered with 'Confirming this sample belongs to v1D1. Due to shipping delays, our site was instructed to use Unscheduled Kits until Kit As arrived.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:49:47
User opened query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 23-OCT-2020. However, this date matches V1D1 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' (Site from DM). User entered '23 Oct 2020'	Jie Ho (b) (4)	02 Nov 2020 20:09:34
	(b) (4), (b) (6)	30 Oct 2020 13:43:31
	Jie Ho (b) (4)	27 Oct 2020 01:53:31

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '12:45'	Jie Ho (b) (4)	27 Oct 2020 01:53:31

US3472130

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered '23 Oct 2020 12:45'	System	27 Oct 2020 01:53:31

US3472130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:48:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23Oct2020 is reported under unscheduled visit in PPD Central lab, however the in EDC it is recorded in visit 1 day 1. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:52:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23Oct2020 is reported under unscheduled visit in PPD Central lab, however the in EDC it is recorded in visit 1 day 1. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Confirming this sample belongs to v1D1. Due to shipping delays, our site was instructed to use Unscheduled Kits until Kit As arrived.' (Site from DM).	Jie Ho (b) (4)	02 Nov 2020 20:09:40
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23Oct2020 is reported under unscheduled visit in PPD Central lab, however the in EDC it is recorded in visit 1 day 1. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:52:52
User entered '23 Oct 2020'	Jie Ho (b) (4)	27 Oct 2020 01:53:41

US3472130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:48:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jie Ho (b) (4)	27 Oct 2020 01:53:41

US3472130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:48:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:53:41

US3472130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:48:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '12:37'	Jie Ho (b) (4)	27 Oct 2020 01:53:41

US3472130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered '23 Oct 2020 12:37'	System	27 Oct 2020 01:53:41

US3472130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:48:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jie Ho (b) (4)	27 Oct 2020 01:53:41

US3472130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:48:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 01:53:41

US3472130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:48:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 01:53:41

US3472130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered empty.	System	27 Oct 2020 01:53:41

US3472130

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 02:03:52

US3472130

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:29:06
User entered 'I'	System	27 Oct 2020 02:03:52

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:28:43', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '147902ae-2c37-445d-82cd-3bf6efac50ed' User entered 'Yes (Y)'	System	23 Oct 2020 17:29:54
	System	23 Oct 2020 17:29:54

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:29:19', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '147902ae-2c37-445d-82cd-3bf6efac50ed' User entered '97.7'	System	23 Oct 2020 17:29:54
	System	23 Oct 2020 17:29:54

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:29:24', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '147902ae-2c37-445d-82cd-3bf6efac50ed' User entered 'No (N)'	System	23 Oct 2020 17:29:54
	System	23 Oct 2020 17:29:54

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:29:29', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '147902ae-2c37-445d-82cd-3bf6efac50ed' User entered '23 Oct 2020 13:29'	System	23 Oct 2020 17:29:54
	System	23 Oct 2020 17:29:54

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '23 Oct 2020 13:16'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '23 Oct 2020 15:46'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:38:41', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'b194b187-ae5f-489d-8ad4-9802be0a13aa' User entered 'Yes (Y)'	System	24 Oct 2020 03:39:02
	System	24 Oct 2020 03:39:02

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:38:47', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'b194b187-ae5f-489d-8ad4-9802be0a13aa' User entered '98.0'	System	24 Oct 2020 03:39:02
	System	24 Oct 2020 03:39:02

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:38:51', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'b194b187-ae5f-489d-8ad4-9802be0a13aa' User entered 'No (N)'	System	24 Oct 2020 03:39:02
	System	24 Oct 2020 03:39:02

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:38:57', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'b194b187-ae5f-489d-8ad4-9802be0a13aa' User entered '23 Oct 2020 23:38'	System	24 Oct 2020 03:39:02
	System	24 Oct 2020 03:39:02

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '23 Oct 2020 16:41'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 2'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:48:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:25', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c1eb884c-da10-4dcc-9285-00678e1fc129' User entered 'Yes (Y)'	System	25 Oct 2020 00:58:37
	System	25 Oct 2020 00:58:37

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:48:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:29', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c1eb884c-da10-4dcc-9285-00678e1fc129' User entered '97.4'	System	25 Oct 2020 00:58:37
	System	25 Oct 2020 00:58:37

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:33', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c1eb884c-da10-4dcc-9285-00678e1fc129'	System	25 Oct 2020 00:58:37
User entered 'No (N)'	System	25 Oct 2020 00:58:37

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:36', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c1eb884c-da10-4dcc-9285-00678e1fc129' User entered '24 Oct 2020 20:58'	System	25 Oct 2020 00:58:37
	System	25 Oct 2020 00:58:37

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 3'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:48:19

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:07', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '7c10d063-71a3-4c9d-8eef-f6c39c38e685'	System	25 Oct 2020 17:07:21
User entered 'Yes (Y)'	System	25 Oct 2020 17:07:21

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:48:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:12', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '7c10d063-71a3-4c9d-8eef-f6c39c38e685' User entered '97.9'	System	25 Oct 2020 17:07:21
	System	25 Oct 2020 17:07:21

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:15', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '7c10d063-71a3-4c9d-8eef-f6c39c38e685'	System	25 Oct 2020 17:07:21
User entered 'No (N)'	System	25 Oct 2020 17:07:21

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:18', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '7c10d063-71a3-4c9d-8eef-f6c39c38e685' User entered '25 Oct 2020 13:07'	System	25 Oct 2020 17:07:21
	System	25 Oct 2020 17:07:21

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 4'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:48:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:02:48', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c122a706-384c-4ead-a127-5a7953fa2c5c' User entered 'Yes (Y)'	System	26 Oct 2020 16:04:40
	System	26 Oct 2020 16:04:40

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:48:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:02:53', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c122a706-384c-4ead-a127-5a7953fa2c5c' User entered '97.7'	System	26 Oct 2020 16:04:40
	System	26 Oct 2020 16:04:40

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:02:56', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c122a706-384c-4ead-a127-5a7953fa2c5c' User entered 'No (N)'	System	26 Oct 2020 16:04:40
	System	26 Oct 2020 16:04:40

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:02:59', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c122a706-384c-4ead-a127-5a7953fa2c5c' User entered '26 Oct 2020 12:02'	System	26 Oct 2020 16:04:40
	System	26 Oct 2020 16:04:40

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 5'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:48:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:15:40', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5251c4ed-01fb-4358-b620-629303f19ed3' User entered 'Yes (Y)'	System	27 Oct 2020 16:15:59
	System	27 Oct 2020 16:15:59

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:48:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:15:46', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5251c4ed-01fb-4358-b620-629303f19ed3' User entered '98.0'	System	27 Oct 2020 16:15:59
	System	27 Oct 2020 16:15:59

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:15:48', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5251c4ed-01fb-4358-b620-629303f19ed3' User entered 'No (N)'	System	27 Oct 2020 16:15:59
	System	27 Oct 2020 16:15:59

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:15:55', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5251c4ed-01fb-4358-b620-629303f19ed3' User entered '27 Oct 2020 12:15'	System	27 Oct 2020 16:15:59
	System	27 Oct 2020 16:15:59

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 6'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:48:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:40:46', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '33409a49-5342-4eaf-b0a6-cd568a82c6e1' User entered 'Yes (Y)'	System	28 Oct 2020 19:41:25
	System	28 Oct 2020 19:41:25

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:48:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:16', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '33409a49-5342-4eaf-b0a6-cd568a82c6e1' User entered '98.4'	System	28 Oct 2020 19:41:25
	System	28 Oct 2020 19:41:25

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:20', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '33409a49-5342-4eaf-b0a6-cd568a82c6e1' User entered 'No (N)'	System	28 Oct 2020 19:41:25
	System	28 Oct 2020 19:41:25

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:22', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '33409a49-5342-4eaf-b0a6-cd568a82c6e1' User entered '28 Oct 2020 15:41'	System	28 Oct 2020 19:41:25
	System	28 Oct 2020 19:41:25

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 7'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:48:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:24:23', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'e4982261-8936-43db-88e8-a20bf70eb4d4' User entered 'Yes (Y)'	System	29 Oct 2020 16:24:37
	System	29 Oct 2020 16:24:37

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:48:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:24:27', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'e4982261-8936-43db-88e8-a20bf70eb4d4' User entered '98.3'	System	29 Oct 2020 16:24:37
	System	29 Oct 2020 16:24:37

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:24:30', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'e4982261-8936-43db-88e8-a20bf70eb4d4' User entered 'No (N)'	System	29 Oct 2020 16:24:37
	System	29 Oct 2020 16:24:37

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:24:32', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'e4982261-8936-43db-88e8-a20bf70eb4d4' User entered '29 Oct 2020 12:24'	System	29 Oct 2020 16:24:37
	System	29 Oct 2020 16:24:37

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:20:26', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0ffa041d-58dc-47f6-9eed-d5dbdfb89568'	System	23 Oct 2020 17:21:29
User entered 'None (1)'	System	23 Oct 2020 17:21:29

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:21:08', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0ffa041d-58dc-47f6-9eed-d5dbdfb89568' User entered 'No (N)'	System	23 Oct 2020 17:21:29
	System	23 Oct 2020 17:21:29

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:21:11', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0ffa041d-58dc-47f6-9eed-d5dbdfb89568'	System	23 Oct 2020 17:21:29
User entered 'No (N)'	System	23 Oct 2020 17:21:29

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:21:16', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0ffa041d-58dc-47f6-9eed-d5dbdfb89568'	System	23 Oct 2020 17:21:29
User entered 'None (1)'	System	23 Oct 2020 17:21:29

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:21:25', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0ffa041d-58dc-47f6-9eed-d5dbdfb89568' User entered '23 Oct 2020 13:21'	System	23 Oct 2020 17:21:29
	System	23 Oct 2020 17:21:29

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '23 Oct 2020 13:16'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '23 Oct 2020 15:46'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:39:02', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '323e7583-95da-41cd-b107-539c9b7116ed' User entered 'None (1)'	System	24 Oct 2020 03:41:43
	System	24 Oct 2020 03:41:43

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:39:15', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '323e7583-95da-41cd-b107-539c9b7116ed' User entered 'Yes (Y)'	System	24 Oct 2020 03:41:43
	System	24 Oct 2020 03:41:43

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:25', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '323e7583-95da-41cd-b107-539c9b7116ed' User entered '2'	System	24 Oct 2020 03:41:43
	System	24 Oct 2020 03:41:43

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:29', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '323e7583-95da-41cd-b107-539c9b7116ed' User entered 'No (N)'	System	24 Oct 2020 03:41:43
	System	24 Oct 2020 03:41:43

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:32', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '323e7583-95da-41cd-b107-539c9b7116ed' User entered 'None (1)'	System	24 Oct 2020 03:41:43
	System	24 Oct 2020 03:41:43

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:40', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '323e7583-95da-41cd-b107-539c9b7116ed' User entered '23 Oct 2020 23:41'	System	24 Oct 2020 03:41:43
	System	24 Oct 2020 03:41:43

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '23 Oct 2020 16:41'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 2'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:57:49', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ac47af3b-a803-4f04-b8bc-7f61f140426e' User entered 'Does not interfere with activity (2)'	System	25 Oct 2020 00:58:23
	System	25 Oct 2020 00:58:23

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:57:47', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ac47af3b-a803-4f04-b8bc-7f61f140426e' User entered 'Yes (Y)'	System	25 Oct 2020 00:58:23
	System	25 Oct 2020 00:58:23

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:57:45', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ac47af3b-a803-4f04-b8bc-7f61f140426e' User entered '2'	System	25 Oct 2020 00:58:23
	System	25 Oct 2020 00:58:23

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:57:44', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ac47af3b-a803-4f04-b8bc-7f61f140426e' User entered 'No (N)'	System	25 Oct 2020 00:58:23
	System	25 Oct 2020 00:58:23

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:07', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ac47af3b-a803-4f04-b8bc-7f61f140426e' User entered 'None (1)'	System	25 Oct 2020 00:58:23
	System	25 Oct 2020 00:58:23

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:16', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ac47af3b-a803-4f04-b8bc-7f61f140426e' User entered '24 Oct 2020 20:58'	System	25 Oct 2020 00:58:23
	System	25 Oct 2020 00:58:23

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 3'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:32', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'be59d1ed-7150-42e9-979b-8b1b3dd2fcbe'	System	25 Oct 2020 17:07:59
User entered 'Does not interfere with activity (2)'	System	25 Oct 2020 17:07:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:34', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'be59d1ed-7150-42e9-979b-8b1b3dd2fcbe' User entered 'Yes (Y)'	System	25 Oct 2020 17:07:59
	System	25 Oct 2020 17:07:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:43', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'be59d1ed-7150-42e9-979b-8b1b3dd2fcbe' User entered '2'	System	25 Oct 2020 17:07:59
	System	25 Oct 2020 17:07:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:46', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'be59d1ed-7150-42e9-979b-8b1b3dd2fcbe' User entered 'No (N)'	System	25 Oct 2020 17:07:59
	System	25 Oct 2020 17:07:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:50', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'be59d1ed-7150-42e9-979b-8b1b3dd2fcbe' User entered 'None (1)'	System	25 Oct 2020 17:07:59
	System	25 Oct 2020 17:07:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:07:58', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'be59d1ed-7150-42e9-979b-8b1b3dd2fcbe' User entered '25 Oct 2020 13:07'	System	25 Oct 2020 17:07:59
	System	25 Oct 2020 17:07:59

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 4'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:24', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5b1ec7fd-2f7b-4ec7-97fc-947731386da0'	System	26 Oct 2020 16:02:25
User entered 'None (1)'	System	26 Oct 2020 16:02:25

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:26', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5b1ec7fd-2f7b-4ec7-97fc-947731386da0' User entered 'Yes (Y)'	System	26 Oct 2020 16:02:25
	System	26 Oct 2020 16:02:25

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:29', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5b1ec7fd-2f7b-4ec7-97fc-947731386da0' User entered '2'	System	26 Oct 2020 16:02:25
	System	26 Oct 2020 16:02:25

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:32', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5b1ec7fd-2f7b-4ec7-97fc-947731386da0' User entered 'No (N)'	System	26 Oct 2020 16:02:25
	System	26 Oct 2020 16:02:25

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:40', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5b1ec7fd-2f7b-4ec7-97fc-947731386da0'	System	26 Oct 2020 16:02:25
User entered 'None (1)'	System	26 Oct 2020 16:02:25

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:43', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5b1ec7fd-2f7b-4ec7-97fc-947731386da0' User entered '26 Oct 2020 12:00'	System	26 Oct 2020 16:02:25
	System	26 Oct 2020 16:02:25

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 5'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:07', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f3a0dd42-8ecc-4b21-9d0a-dfd90a084860'	System	27 Oct 2020 16:16:27
User entered 'None (1)'	System	27 Oct 2020 16:16:27

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:09', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f3a0dd42-8ecc-4b21-9d0a-dfd90a084860' User entered 'Yes (Y)'	System	27 Oct 2020 16:16:27
	System	27 Oct 2020 16:16:27

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:14', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f3a0dd42-8ecc-4b21-9d0a-dfd90a084860' User entered '2'	System	27 Oct 2020 16:16:27
	System	27 Oct 2020 16:16:27

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:17', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f3a0dd42-8ecc-4b21-9d0a-dfd90a084860' User entered 'No (N)'	System	27 Oct 2020 16:16:27
	System	27 Oct 2020 16:16:27

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:19', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f3a0dd42-8ecc-4b21-9d0a-dfd90a084860' User entered 'None (1)'	System	27 Oct 2020 16:16:27
	System	27 Oct 2020 16:16:27

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:24', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f3a0dd42-8ecc-4b21-9d0a-dfd90a084860' User entered '27 Oct 2020 12:16'	System	27 Oct 2020 16:16:27
	System	27 Oct 2020 16:16:27

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 6'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:27', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '822be881-fabf-4fad-aa9c-ce613b8d2211'	System	28 Oct 2020 19:41:50
User entered 'None (1)'	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:35', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '822be881-fabf-4fad-aa9c-ce613b8d2211' User entered 'Yes (Y)'	System	28 Oct 2020 19:41:50
	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:41', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '822be881-fabf-4fad-aa9c-ce613b8d2211' User entered '1'	System	28 Oct 2020 19:41:50
	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:43', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '822be881-fabf-4fad-aa9c-ce613b8d2211' User entered 'No (N)'	System	28 Oct 2020 19:41:50
	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:45', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '822be881-fabf-4fad-aa9c-ce613b8d2211' User entered 'None (1)'	System	28 Oct 2020 19:41:50
	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:48', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '822be881-fabf-4fad-aa9c-ce613b8d2211' User entered '28 Oct 2020 15:41'	System	28 Oct 2020 19:41:50
	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 7'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:23', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'bac2b93c-1ef2-407c-bfd6-24e8e99590ce'	System	29 Oct 2020 16:23:42
User entered 'None (1)'	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:25', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'bac2b93c-1ef2-407c-bfd6-24e8e99590ce' User entered 'Yes (Y)'	System	29 Oct 2020 16:23:42
	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:33', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'bac2b93c-1ef2-407c-bfd6-24e8e99590ce' User entered '1'	System	29 Oct 2020 16:23:42
	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:35', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'bac2b93c-1ef2-407c-bfd6-24e8e99590ce' User entered 'No (N)'	System	29 Oct 2020 16:23:42
	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:37', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'bac2b93c-1ef2-407c-bfd6-24e8e99590ce'	System	29 Oct 2020 16:23:42
User entered 'None (1)'	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:40', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'bac2b93c-1ef2-407c-bfd6-24e8e99590ce' User entered '29 Oct 2020 12:23'	System	29 Oct 2020 16:23:42
	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:22:01', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e99ca47-19ed-4471-b95f-6e6d77c82884'	System	23 Oct 2020 17:22:32
User entered 'No interference with activity (1)'	System	23 Oct 2020 17:22:32

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:22:08', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e99ca47-19ed-4471-b95f-6e6d77c82884'	System	23 Oct 2020 17:22:32
User entered 'No interference with activity (1)'	System	23 Oct 2020 17:22:32

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:22:11', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e99ca47-19ed-4471-b95f-6e6d77c82884' User entered 'None (0)'	System	23 Oct 2020 17:22:32
	System	23 Oct 2020 17:22:32

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:22:13', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e99ca47-19ed-4471-b95f-6e6d77c82884' User entered 'None (0)'	System	23 Oct 2020 17:22:32
	System	23 Oct 2020 17:22:32

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:22:16', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e99ca47-19ed-4471-b95f-6e6d77c82884' User entered 'None (0)'	System	23 Oct 2020 17:22:32
	System	23 Oct 2020 17:22:32

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:22:18', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e99ca47-19ed-4471-b95f-6e6d77c82884' User entered 'None (0)'	System	23 Oct 2020 17:22:32
	System	23 Oct 2020 17:22:32

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:22:23', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e99ca47-19ed-4471-b95f-6e6d77c82884' User entered 'No (N)'	System	23 Oct 2020 17:22:32
	System	23 Oct 2020 17:22:32

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T13:22:30', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e99ca47-19ed-4471-b95f-6e6d77c82884' User entered '23 Oct 2020 13:22'	System	23 Oct 2020 17:22:32
	System	23 Oct 2020 17:22:32

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '23 Oct 2020 13:16'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '23 Oct 2020 15:46'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:44', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a4a71d12-34da-4e92-9438-fcce858d903f' User entered 'No interference with activity (1)'	System	24 Oct 2020 03:42:08
	System	24 Oct 2020 03:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:47', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a4a71d12-34da-4e92-9438-fcce858d903f' User entered 'No interference with activity (1)'	System	24 Oct 2020 03:42:08
	System	24 Oct 2020 03:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:50', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a4a71d12-34da-4e92-9438-fcce858d903f' User entered 'None (0)'	System	24 Oct 2020 03:42:08
	System	24 Oct 2020 03:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:52', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a4a71d12-34da-4e92-9438-fcce858d903f' User entered 'None (0)'	System	24 Oct 2020 03:42:08
	System	24 Oct 2020 03:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:54', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a4a71d12-34da-4e92-9438-fcce858d903f' User entered 'None (0)'	System	24 Oct 2020 03:42:08
	System	24 Oct 2020 03:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:56', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a4a71d12-34da-4e92-9438-fcce858d903f' User entered 'None (0)'	System	24 Oct 2020 03:42:08
	System	24 Oct 2020 03:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:41:59', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a4a71d12-34da-4e92-9438-fcce858d903f' User entered 'No (N)'	System	24 Oct 2020 03:42:08
	System	24 Oct 2020 03:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-23T23:42:06', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a4a71d12-34da-4e92-9438-fcce858d903f' User entered '23 Oct 2020 23:42'	System	24 Oct 2020 03:42:08
	System	24 Oct 2020 03:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '23 Oct 2020 16:41'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 2'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:40', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2c68752b-6504-4a37-8a20-b2eae6c2e65d' User entered 'None (0)'	System	25 Oct 2020 00:58:57
	System	25 Oct 2020 00:58:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:41', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2c68752b-6504-4a37-8a20-b2eae6c2e65d' User entered 'None (0)'	System	25 Oct 2020 00:58:57
	System	25 Oct 2020 00:58:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:43', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2c68752b-6504-4a37-8a20-b2eae6c2e65d' User entered 'None (0)'	System	25 Oct 2020 00:58:57
	System	25 Oct 2020 00:58:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:45', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2c68752b-6504-4a37-8a20-b2eae6c2e65d' User entered 'None (0)'	System	25 Oct 2020 00:58:57
	System	25 Oct 2020 00:58:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:47', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2c68752b-6504-4a37-8a20-b2eae6c2e65d' User entered 'None (0)'	System	25 Oct 2020 00:58:57
	System	25 Oct 2020 00:58:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:49', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2c68752b-6504-4a37-8a20-b2eae6c2e65d' User entered 'None (0)'	System	25 Oct 2020 00:58:57
	System	25 Oct 2020 00:58:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:51', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2c68752b-6504-4a37-8a20-b2eae6c2e65d' User entered 'No (N)'	System	25 Oct 2020 00:58:57
	System	25 Oct 2020 00:58:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-24T20:58:55', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2c68752b-6504-4a37-8a20-b2eae6c2e65d' User entered '24 Oct 2020 20:58'	System	25 Oct 2020 00:58:57
	System	25 Oct 2020 00:58:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 3'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:08:01', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '96bce343-12f9-4338-8452-a21894ac8ef2' User entered 'None (0)'	System	25 Oct 2020 17:08:21
	System	25 Oct 2020 17:08:21

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:08:03', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '96bce343-12f9-4338-8452-a21894ac8ef2' User entered 'None (0)'	System	25 Oct 2020 17:08:21
	System	25 Oct 2020 17:08:21

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:08:04', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '96bce343-12f9-4338-8452-a21894ac8ef2' User entered 'None (0)'	System	25 Oct 2020 17:08:21
	System	25 Oct 2020 17:08:21

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:08:07', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '96bce343-12f9-4338-8452-a21894ac8ef2' User entered 'None (0)'	System	25 Oct 2020 17:08:21
	System	25 Oct 2020 17:08:21

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:08:09', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '96bce343-12f9-4338-8452-a21894ac8ef2' User entered 'None (0)'	System	25 Oct 2020 17:08:21
	System	25 Oct 2020 17:08:21

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:08:10', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '96bce343-12f9-4338-8452-a21894ac8ef2' User entered 'None (0)'	System	25 Oct 2020 17:08:21
	System	25 Oct 2020 17:08:21

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:08:13', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '96bce343-12f9-4338-8452-a21894ac8ef2' User entered 'No (N)'	System	25 Oct 2020 17:08:21
	System	25 Oct 2020 17:08:21

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-25T13:08:16', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '96bce343-12f9-4338-8452-a21894ac8ef2' User entered '25 Oct 2020 13:08'	System	25 Oct 2020 17:08:21
	System	25 Oct 2020 17:08:21

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 4'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:46', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f590f387-ea0e-4d16-98b5-33b04444ca89' User entered 'None (0)'	System	26 Oct 2020 16:02:47
	System	26 Oct 2020 16:02:47

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:47', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f590f387-ea0e-4d16-98b5-33b04444ca89' User entered 'None (0)'	System	26 Oct 2020 16:02:47
	System	26 Oct 2020 16:02:47

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:49', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f590f387-ea0e-4d16-98b5-33b04444ca89' User entered 'None (0)'	System	26 Oct 2020 16:02:47
	System	26 Oct 2020 16:02:47

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:50', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f590f387-ea0e-4d16-98b5-33b04444ca89' User entered 'None (0)'	System	26 Oct 2020 16:02:47
	System	26 Oct 2020 16:02:47

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:51', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f590f387-ea0e-4d16-98b5-33b04444ca89' User entered 'None (0)'	System	26 Oct 2020 16:02:47
	System	26 Oct 2020 16:02:47

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:53', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f590f387-ea0e-4d16-98b5-33b04444ca89' User entered 'None (0)'	System	26 Oct 2020 16:02:47
	System	26 Oct 2020 16:02:47

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:55', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f590f387-ea0e-4d16-98b5-33b04444ca89' User entered 'No (N)'	System	26 Oct 2020 16:02:47
	System	26 Oct 2020 16:02:47

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-26T12:00:58', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'f590f387-ea0e-4d16-98b5-33b04444ca89' User entered '26 Oct 2020 12:00'	System	26 Oct 2020 16:02:47
	System	26 Oct 2020 16:02:47

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 5'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:27', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '261653dd-638f-4469-88b2-230cbb8929bb' User entered 'None (0)'	System	27 Oct 2020 16:16:57
	System	27 Oct 2020 16:16:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:30', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '261653dd-638f-4469-88b2-230cbb8929bb' User entered 'None (0)'	System	27 Oct 2020 16:16:57
	System	27 Oct 2020 16:16:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:32', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '261653dd-638f-4469-88b2-230cbb8929bb' User entered 'None (0)'	System	27 Oct 2020 16:16:57
	System	27 Oct 2020 16:16:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:35', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '261653dd-638f-4469-88b2-230cbb8929bb' User entered 'None (0)'	System	27 Oct 2020 16:16:57
	System	27 Oct 2020 16:16:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:37', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '261653dd-638f-4469-88b2-230cbb8929bb' User entered 'None (0)'	System	27 Oct 2020 16:16:57
	System	27 Oct 2020 16:16:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:45', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '261653dd-638f-4469-88b2-230cbb8929bb' User entered 'None (0)'	System	27 Oct 2020 16:16:57
	System	27 Oct 2020 16:16:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:48', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '261653dd-638f-4469-88b2-230cbb8929bb' User entered 'No (N)'	System	27 Oct 2020 16:16:57
	System	27 Oct 2020 16:16:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-27T12:16:53', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '261653dd-638f-4469-88b2-230cbb8929bb' User entered '27 Oct 2020 12:16'	System	27 Oct 2020 16:16:57
	System	27 Oct 2020 16:16:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 6'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:51', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e1c3b67-40e3-41ee-a194-6de631a8ba38' User entered 'None (0)'	System	28 Oct 2020 19:42:08
	System	28 Oct 2020 19:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:52', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e1c3b67-40e3-41ee-a194-6de631a8ba38' User entered 'None (0)'	System	28 Oct 2020 19:42:08
	System	28 Oct 2020 19:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:53', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e1c3b67-40e3-41ee-a194-6de631a8ba38' User entered 'None (0)'	System	28 Oct 2020 19:42:08
	System	28 Oct 2020 19:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:55', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e1c3b67-40e3-41ee-a194-6de631a8ba38' User entered 'None (0)'	System	28 Oct 2020 19:42:08
	System	28 Oct 2020 19:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:56', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e1c3b67-40e3-41ee-a194-6de631a8ba38' User entered 'None (0)'	System	28 Oct 2020 19:42:08
	System	28 Oct 2020 19:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:41:58', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e1c3b67-40e3-41ee-a194-6de631a8ba38' User entered 'None (0)'	System	28 Oct 2020 19:42:08
	System	28 Oct 2020 19:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:42:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e1c3b67-40e3-41ee-a194-6de631a8ba38' User entered 'No (N)'	System	28 Oct 2020 19:42:08
	System	28 Oct 2020 19:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-28T15:42:02', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1e1c3b67-40e3-41ee-a194-6de631a8ba38' User entered '28 Oct 2020 15:42'	System	28 Oct 2020 19:42:08
	System	28 Oct 2020 19:42:08

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	23 Oct 2020 17:18:53
User entered 'Day 7'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:42', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '9c685911-2ef1-4d4e-b6b0-25aea2dd507b' User entered 'None (0)'	System	29 Oct 2020 16:23:57
	System	29 Oct 2020 16:23:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:43', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '9c685911-2ef1-4d4e-b6b0-25aea2dd507b' User entered 'None (0)'	System	29 Oct 2020 16:23:57
	System	29 Oct 2020 16:23:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:44', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '9c685911-2ef1-4d4e-b6b0-25aea2dd507b' User entered 'None (0)'	System	29 Oct 2020 16:23:57
	System	29 Oct 2020 16:23:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:46', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '9c685911-2ef1-4d4e-b6b0-25aea2dd507b' User entered 'None (0)'	System	29 Oct 2020 16:23:57
	System	29 Oct 2020 16:23:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:47', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '9c685911-2ef1-4d4e-b6b0-25aea2dd507b' User entered 'None (0)'	System	29 Oct 2020 16:23:57
	System	29 Oct 2020 16:23:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:48', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '9c685911-2ef1-4d4e-b6b0-25aea2dd507b' User entered 'None (0)'	System	29 Oct 2020 16:23:57
	System	29 Oct 2020 16:23:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:50', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '9c685911-2ef1-4d4e-b6b0-25aea2dd507b' User entered 'No (N)'	System	29 Oct 2020 16:23:57
	System	29 Oct 2020 16:23:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-29T12:23:53', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '9c685911-2ef1-4d4e-b6b0-25aea2dd507b' User entered '29 Oct 2020 12:23'	System	29 Oct 2020 16:23:57
	System	29 Oct 2020 16:23:57

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 17:18:53

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	28 Oct 2020 19:41:50
User entered 'Day 8'	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-30T23:59:24', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2919b546-3395-4de3-bf88-c51ca40a5add' User entered 'Yes (Y)'	System	31 Oct 2020 03:59:40
	System	31 Oct 2020 03:59:40

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-30T23:59:27', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2919b546-3395-4de3-bf88-c51ca40a5add' User entered '1'	System	31 Oct 2020 03:59:40
	System	31 Oct 2020 03:59:40

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-30T23:59:34', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2919b546-3395-4de3-bf88-c51ca40a5add' User entered '30 Oct 2020 23:59'	System	31 Oct 2020 03:59:40
	System	31 Oct 2020 03:59:40

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	29 Oct 2020 16:23:42
User entered 'Day 9'	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	31 Oct 2020 03:59:40
User entered 'Day 10'	System	31 Oct 2020 03:59:40

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-01T15:25:13', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0dddec47-02cc-49aa-a010-719154792ae5' User entered 'Yes (Y)'	System	01 Nov 2020 20:25:20
	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-01T15:25:15', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0dddec47-02cc-49aa-a010-719154792ae5' User entered '1'	System	01 Nov 2020 20:25:20
	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-01T15:25:18', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0dddec47-02cc-49aa-a010-719154792ae5' User entered '01 Nov 2020 15:25'	System	01 Nov 2020 20:25:20
	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '01 Nov 2020 12:00'	System	31 Oct 2020 03:59:40

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '02 Nov 2020 11:59'	System	31 Oct 2020 03:59:40

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	01 Nov 2020 20:25:20
User entered 'Day 11'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-03T00:52:31', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8b4d42cb-a26d-4528-9aeb-6f8ad96449f5' User entered 'Yes (Y)'	System	03 Nov 2020 05:52:42
	System	03 Nov 2020 05:52:42

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 11 Aug 2021 22:48:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-03T00:52:35', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8b4d42cb-a26d-4528-9aeb-6f8ad96449f5' User entered '1'	System	03 Nov 2020 05:52:42
	System	03 Nov 2020 05:52:42

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-03T00:52:38', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8b4d42cb-a26d-4528-9aeb-6f8ad96449f5' User entered '03 Nov 2020 00:52'	System	03 Nov 2020 05:52:42
	System	03 Nov 2020 05:52:42

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '02 Nov 2020 12:00'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '03 Nov 2020 11:59'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	01 Nov 2020 20:25:20
User entered 'Day 12'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 11 Aug 2021 22:48:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-03T12:08:37', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'd96dab8e-cefb-42ae-b511-cdbcc7de9511' User entered 'No (N)'	System	03 Nov 2020 17:08:43
	System	03 Nov 2020 17:08:43

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 11 Aug 2021 22:48:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-03T12:08:40', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'd96dab8e-cefb-42ae-b511-cdbcc7de9511' User entered '03 Nov 2020 12:08'	System	03 Nov 2020 17:08:43
	System	03 Nov 2020 17:08:43

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	28 Oct 2020 19:41:50
User entered 'Day 8'	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-30T23:59:39', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ceed9890-4b28-4250-bdf0-62c73e142b00'	System	31 Oct 2020 03:59:43
User entered 'No (N)'	System	31 Oct 2020 03:59:43

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-10-30T23:59:42', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ceed9890-4b28-4250-bdf0-62c73e142b00' User entered '30 Oct 2020 23:59'	System	31 Oct 2020 03:59:43
	System	31 Oct 2020 03:59:43

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 19:41:50

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	29 Oct 2020 16:23:42
User entered 'Day 9'	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 16:23:42

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	31 Oct 2020 03:59:40
User entered 'Day 10'	System	31 Oct 2020 03:59:40

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-01T15:25:21', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '82fb6884-3a86-405a-9981-5e483313469e' User entered 'No (N)'	System	01 Nov 2020 20:25:26
	System	01 Nov 2020 20:25:26

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-01T15:25:24', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '82fb6884-3a86-405a-9981-5e483313469e' User entered '01 Nov 2020 15:25'	System	01 Nov 2020 20:25:26
	System	01 Nov 2020 20:25:26

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '01 Nov 2020 12:00'	System	31 Oct 2020 03:59:40

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '02 Nov 2020 11:59'	System	31 Oct 2020 03:59:40

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	01 Nov 2020 20:25:20
User entered 'Day 11'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-03T00:52:41', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2b7acc60-7b0f-43fe-bdc0-e6781cb0580b' User entered 'No (N)'	System	03 Nov 2020 05:52:47
	System	03 Nov 2020 05:52:47

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-03T00:52:44', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '2b7acc60-7b0f-43fe-bdc0-e6781cb0580b' User entered '03 Nov 2020 00:52'	System	03 Nov 2020 05:52:47
	System	03 Nov 2020 05:52:47

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '02 Nov 2020 12:00'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '03 Nov 2020 11:59'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
Data entry locked.	System	01 Nov 2020 20:25:20
User entered 'Day 12'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:48:19

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 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-03T12:08:45', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1fe81f41-58c5-4be6-994b-a2e588e1ca72'	System	03 Nov 2020 17:08:53
User entered 'No (N)'	System	03 Nov 2020 17:08:53

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:48:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC056874-5AB4-47E3-832F-348562B13FC7)', Time: '2020-11-03T12:08:47', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '1fe81f41-58c5-4be6-994b-a2e588e1ca72' User entered '03 Nov 2020 12:08'	System	03 Nov 2020 17:08:53
	System	03 Nov 2020 17:08:53

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:48:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 20:25:20

US3472130

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:48:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:27:38
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 20:25:20

US3472130

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:56
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:22:33

US3472130

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:56
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:22:33

US3472130

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:56
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:22:33

US3472130

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:56
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:22:33

US3472130

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:56
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:22:38

US3472130

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:56
User entered 'I'	System	06 Nov 2020 16:22:38

US3472130

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:16:50

US3472130

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	09 Nov 2020 21:17:00
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	09 Nov 2020 21:17:00
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	09 Nov 2020 21:17:00
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:17:00
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	09 Nov 2020 21:16:50
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Nov 2020 21:16:50
User entered '16 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 21:16:50

US3472130

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:16:50

US3472130

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:16:50

US3472130

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:17:04

US3472130

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:14
User entered 'I'	System	09 Nov 2020 21:17:04

US3472130

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:20
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:00

US3472130

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:20
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:00

US3472130

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:20
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:00

US3472130

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:20
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:00

US3472130

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:20
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:03

US3472130

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:20
User entered 'I'	System	07 Dec 2020 19:43:03

US3472130

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:09

US3472130

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:09

US3472130

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[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 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:09

US3472130

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'VISIT2'	System	07 Dec 2020 19:43:09

US3472130

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:17

US3472130

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'I'	System	07 Dec 2020 19:43:17

US3472130

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:30

US3472130

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:30

US3472130

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:30

US3472130

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:30

US3472130

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:33

US3472130

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'I'	System	07 Dec 2020 19:43:33

US3472130

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:46

US3472130

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:46

US3472130

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:46

US3472130

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:46

US3472130

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:49

US3472130

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'I'	System	07 Dec 2020 19:43:49

US3472130

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:59

US3472130

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:59

US3472130

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:59

US3472130

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:43:59

US3472130

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:44:02

US3472130

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'I'	System	07 Dec 2020 19:44:02

US3472130

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) Christopher Chianese (b) (4)	21 Dec 2020 19:53:32

US3472130

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '21 Dec 2020'	(b) (4) Christopher Chianese (b) (4)	21 Dec 2020 19:53:32

US3472130

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[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 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Clinic (Clinic)'	Christopher Chianese (b) (4)	21 Dec 2020 19:53:32

US3472130

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'VISIT3'	System	21 Dec 2020 19:53:32

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '14:35'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered '21 Dec 2020 14:35'	System	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '95'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'bpm'	System	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'breaths/min'	System	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '138'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'mmHg'	System	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '78'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'mmHg'	System	21 Dec 2020 23:21:59

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48

US3472130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48

US3472130

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:22:05

US3472130

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:22:05

US3472130

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:22:27

US3472130

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:22:27

US3472130

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '14:40'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:22:27

US3472130

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered '21 Dec 2020 14:40'	System	21 Dec 2020 23:22:27

US3472130

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:22:33

US3472130

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'I'	System	21 Dec 2020 23:22:33

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-01-17T02:19:10', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0e0caa75-ef1f-4593-9b15-1ae13ff1cf49'	System	17 Jan 2021 07:19:24
User entered 'No (N)'	System	17 Jan 2021 07:19:24

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-01-17T02:19:15', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0e0caa75-ef1f-4593-9b15-1ae13ff1cf49'	System	17 Jan 2021 07:19:24
User entered 'No (N)'	System	17 Jan 2021 07:19:24

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-01-17T02:19:19', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0e0caa75-ef1f-4593-9b15-1ae13ff1cf49' User entered '17 Jan 2021 02:19:19'	System	17 Jan 2021 07:19:24
	System	17 Jan 2021 07:19:24

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-01-24T02:08:34', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8a8b87b5-c365-45df-be47-6156db36567b' User entered 'No (N)'	System	24 Jan 2021 07:08:43
	System	24 Jan 2021 07:08:43

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-01-24T02:08:38', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8a8b87b5-c365-45df-be47-6156db36567b'	System	24 Jan 2021 07:08:43
User entered 'No (N)'	System	24 Jan 2021 07:08:43

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-01-24T02:08:41', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8a8b87b5-c365-45df-be47-6156db36567b' User entered '24 Jan 2021 02:08:41'	System	24 Jan 2021 07:08:43
	System	24 Jan 2021 07:08:43

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-01-31T11:15:15', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'cf788f73-a337-448b-899f-a32bcd9bc0b3'	System	31 Jan 2021 16:15:24
User entered 'No (N)'	System	31 Jan 2021 16:15:24

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-01-31T11:15:19', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'cf788f73-a337-448b-899f-a32bcd9bc0b3'	System	31 Jan 2021 16:15:24
User entered 'No (N)'	System	31 Jan 2021 16:15:24

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-01-31T11:15:22', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'cf788f73-a337-448b-899f-a32bcd9bc0b3' User entered '31 Jan 2021 11:15:22'	System	31 Jan 2021 16:15:24
	System	31 Jan 2021 16:15:24

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-09T12:50:24', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c2406ac1-7b16-4538-8cf7-47a1a29d7808'	System	09 Feb 2021 17:50:39
User entered 'No (N)'	System	09 Feb 2021 17:50:39

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-09T12:50:29', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c2406ac1-7b16-4538-8cf7-47a1a29d7808' User entered 'No (N)'	System	09 Feb 2021 17:50:39
	System	09 Feb 2021 17:50:39

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-09T12:50:34', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c2406ac1-7b16-4538-8cf7-47a1a29d7808' User entered '09 Feb 2021 12:50:34'	System	09 Feb 2021 17:50:39
	System	09 Feb 2021 17:50:39

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-14T00:33:46', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '57755662-60c0-459d-b90a-7eed98bd3dda' User entered 'No (N)'	System	14 Feb 2021 05:33:56

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-14T00:33:50', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '57755662-60c0-459d-b90a-7eed98bd3dda'	System	14 Feb 2021 05:33:56
User entered 'No (N)'	System	14 Feb 2021 05:33:56

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-14T00:33:53', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '57755662-60c0-459d-b90a-7eed98bd3dda' User entered '14 Feb 2021 00:33:53'	System	14 Feb 2021 05:33:56
	System	14 Feb 2021 05:33:56

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-21T01:17:47', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8085f13d-f620-454f-9cde-a14c459942bd' User entered 'No (N)'	System	21 Feb 2021 06:17:56
	System	21 Feb 2021 06:17:56

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-21T01:17:49', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8085f13d-f620-454f-9cde-a14c459942bd' User entered 'No (N)'	System	21 Feb 2021 06:17:56
	System	21 Feb 2021 06:17:56

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-21T01:17:53', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8085f13d-f620-454f-9cde-a14c459942bd' User entered '21 Feb 2021 01:17:53'	System	21 Feb 2021 06:17:56
	System	21 Feb 2021 06:17:56

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-28T01:07:28-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '54500f45-0957-4806-96c8-acc3452e8bc1' User entered 'No (N)'	System	28 Feb 2021 06:07:36
	System	28 Feb 2021 06:07:36

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-28T01:07:30-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '54500f45-0957-4806-96c8-acc3452e8bc1' User entered 'No (N)'	System	28 Feb 2021 06:07:36
	System	28 Feb 2021 06:07:36

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-28T01:07:33-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '54500f45-0957-4806-96c8-acc3452e8bc1' User entered '28 Feb 2021 06:07:33'	System	28 Feb 2021 06:07:36
	System	28 Feb 2021 06:07:36

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-11T10:08:52-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0616ac0a-9db9-48b2-bcc5-f1e060ae3129'	System	11 Mar 2021 15:09:04
User entered 'No (N)'	System	11 Mar 2021 15:09:04

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-11T10:08:55-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0616ac0a-9db9-48b2-bcc5-f1e060ae3129'	System	11 Mar 2021 15:09:04
User entered 'No (N)'	System	11 Mar 2021 15:09:04

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-11T10:08:58-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '0616ac0a-9db9-48b2-bcc5-f1e060ae3129' User entered '11 Mar 2021 10:08:58'	System	11 Mar 2021 15:09:04
	System	11 Mar 2021 15:09:04

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-14T00:29:33-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5c867d41-6c62-43cc-a0e9-4a8817d750f3'	System	14 Mar 2021 05:42:19
User entered 'No (N)'	System	14 Mar 2021 05:42:19

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-14T00:29:35-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5c867d41-6c62-43cc-a0e9-4a8817d750f3'	System	14 Mar 2021 05:42:19
User entered 'No (N)'	System	14 Mar 2021 05:42:19

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-14T00:29:38-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '5c867d41-6c62-43cc-a0e9-4a8817d750f3' User entered '14 Mar 2021 00:29:38'	System	14 Mar 2021 05:42:19
	System	14 Mar 2021 05:42:19

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-21T00:02:14-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ccc63850-da72-4ee8-9247-b69ccef3960e' User entered 'No (N)'	System	21 Mar 2021 04:02:53
	System	21 Mar 2021 04:02:53

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-21T00:02:18-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ccc63850-da72-4ee8-9247-b69ccef3960e' User entered 'No (N)'	System	21 Mar 2021 04:02:53

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-21T00:02:21-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'ccc63850-da72-4ee8-9247-b69ccef3960e' User entered '21 Mar 2021 00:02:21'	System	21 Mar 2021 04:02:53
	System	21 Mar 2021 04:02:53

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-28T02:24:19-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '4326b73e-3489-49e8-ad02-5f4fa222693e' User entered 'No (N)'	System	28 Mar 2021 06:24:26
	System	28 Mar 2021 06:24:26

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-28T02:24:22-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '4326b73e-3489-49e8-ad02-5f4fa222693e'	System	28 Mar 2021 06:24:26
User entered 'No (N)'	System	28 Mar 2021 06:24:26

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-03-28T02:24:24-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '4326b73e-3489-49e8-ad02-5f4fa222693e' User entered '28 Mar 2021 02:24:24'	System	28 Mar 2021 06:24:26
	System	28 Mar 2021 06:24:26

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-04T00:04:39-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c71889e1-ba54-4d92-b62f-fa85fb65ec35'	System	04 Apr 2021 04:04:48
User entered 'No (N)'	System	04 Apr 2021 04:04:48

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-04T00:04:41-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c71889e1-ba54-4d92-b62f-fa85fb65ec35'	System	04 Apr 2021 04:04:48
User entered 'No (N)'	System	04 Apr 2021 04:04:48

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-04T00:04:43-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'c71889e1-ba54-4d92-b62f-fa85fb65ec35'	System	04 Apr 2021 04:04:48
User entered '04 Apr 2021 00:04:43'	System	04 Apr 2021 04:04:48

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-11T00:27:22-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '44707c20-7ead-42df-8e20-5d9e97c18777'	System	11 Apr 2021 04:27:31
User entered 'No (N)'	System	11 Apr 2021 04:27:31

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-11T00:27:25-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '44707c20-7ead-42df-8e20-5d9e97c18777'	System	11 Apr 2021 04:27:31
User entered 'No (N)'	System	11 Apr 2021 04:27:31

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-11T00:27:28-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '44707c20-7ead-42df-8e20-5d9e97c18777'	System	11 Apr 2021 04:27:31
User entered '11 Apr 2021 00:27:28'	System	11 Apr 2021 04:27:31

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-18T11:55:38-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8614ec3f-e463-412c-a3a4-833da0472b3d' User entered 'No (N)'	System	18 Apr 2021 15:55:47
	System	18 Apr 2021 15:55:47

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-18T11:55:41-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8614ec3f-e463-412c-a3a4-833da0472b3d'	System	18 Apr 2021 15:55:47
User entered 'No (N)'	System	18 Apr 2021 15:55:47

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-18T11:55:44-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '8614ec3f-e463-412c-a3a4-833da0472b3d'	System	18 Apr 2021 15:55:47
User entered '18 Apr 2021 11:55:44'	System	18 Apr 2021 15:55:47

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-25T02:42:47-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '79328d30-3579-4c1e-ab3f-e982be6cc450' User entered 'No (N)'	System	25 Apr 2021 06:42:54
	System	25 Apr 2021 06:42:54

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

Have you been exposed to someone with 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 (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-25T02:42:49-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '79328d30-3579-4c1e-ab3f-e982be6cc450'	System	25 Apr 2021 06:42:54
User entered 'No (N)'	System	25 Apr 2021 06:42:54

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-04-25T02:42:51-04:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: '79328d30-3579-4c1e-ab3f-e982be6cc450'	System	25 Apr 2021 06:42:54
User entered '25 Apr 2021 02:42:51'	System	25 Apr 2021 06:42:54

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '25 Dec 2022 00:01'	System	20 Nov 2020 13:40:37

US3472130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:48:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:40:37
Amendment Manager: User entered '29 Dec 2022 23:59'	System	20 Nov 2020 13:40:37

US3472130

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:48:19

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 12:51:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-28T01:07:38-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a20f3bee-1301-45c8-aad4-66025ad60019'	System	28 Feb 2021 06:07:43
User entered 'No (N)'	System	28 Feb 2021 06:07:43

US3472130

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:48:19

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:51:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BEF660E-8F56-4DC1-A03A-EC1EC01A92A2)', Time: '2021-02-28T01:07:41-05:00', User OID: 'PatientReportedOutcome (US3472130)', ODM File OID: 'a20f3bee-1301-45c8-aad4-66025ad60019' User entered '28 Feb 2021 06:07:41'	System	28 Feb 2021 06:07:43
	System	28 Feb 2021 06:07:43

US3472130

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:15:42

US3472130

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:15:42

US3472130

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:15:42

US3472130

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:15:42

US3472130

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:05:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:15:46

US3472130

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:48
User entered 'I'	System	13 Jan 2021 16:15:46

US3472130

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:07:13
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:00:15

US3472130

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:07:13
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:00:15

US3472130

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:07:13
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:00:15

US3472130

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:07:13
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:00:15

US3472130

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:07:13
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:00:20

US3472130

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:07:13
User entered 'I'	System	17 Feb 2021 14:00:20

US3472130

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:14:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 23:42:10

US3472130

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:14:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 23:42:10

US3472130

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:14:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 23:42:10

US3472130

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:14:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 23:42:10

US3472130

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:14:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 23:42:14

US3472130

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:14:22
User entered 'I'	System	17 Mar 2021 23:42:14

US3472130

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:15

US3472130

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:15

US3472130

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:15

US3472130

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:15

US3472130

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:20

US3472130

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 13:42:20

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:48:19

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:22
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).	(b) (4), (b) (6)	17 Nov 2020 02:21:18
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 'Thank you for your guidance. I attended the training on 9/4/2020 but cannot seem to locate the slides sent from that training. I have asked our CRA to resend them. Severity Assessment has been updated.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 16:57:17
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 12:37:45
User closed query 'Please reconcile and add severity log as required' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:37:45
Query 'Please reconcile and add severity log as required' answered with 'Response provided on symptom log. We are in communication with our CRA on when to complete the severity assessment form. Any guidance you may be able provide would be appreciated as we are not clear as to when exactly after a positive result is determined that the severity assessment should be completed.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:05:59
User opened query 'Please reconcile and add severity log as required' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:45:27
User entered '06 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 21:18:55

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:48:19

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:22
User entered '14:20'	(b) (4), (b) (6)	09 Nov 2020 21:18:55

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:48:19

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '06 Nov 2020 14:20'	System	09 Nov 2020 21:18:55

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:48:19

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:22
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	09 Nov 2020 21:18:55

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:48:19

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 21:18:55

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	17 Nov 2020 03:48:46
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:52:56
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
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).		20 Nov 2020 04:37:48
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 log to accurately reflect the correct SymptomDays.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 16:54:46
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 12:37:32
User closed query 'Please reconcile as AE start date = 03Nov2020. Symptom log day 1 = day subject first experienced symptoms per CCGs and training provided to sites' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:37:32
Query 'Please reconcile as AE start date = 03Nov2020. Symptom log day 1 = day subject first experienced symptoms per CCGs and training provided to sites' answered with 'The CCGs also state "Log must be completed for 14 days from Illness Day 1 or until symptoms resolve for participants that are confirmed SARs-CoV-2 positive". The protocol also states that Day 1 is the Illness Day 1 Visit. The guidelines as we read them appear to be contradictory.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:03:02
User opened query 'Please reconcile as AE start date = 03Nov2020. Symptom log day 1 = day subject first experienced symptoms per CCGs and training provided to sites' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:45:05

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '98'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '99.0' F	(b) (4), (b) (6)	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Nov 2020 21:19:59

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	17 Nov 2020 03:48:46
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:52:56
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '97'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '101.3' F	(b) (4), (b) (6)	10 Nov 2020 20:31:29

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Nov 2020 20:31:29

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	17 Nov 2020 03:48:46
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:52:56
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '11 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '96'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '100.1' F	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'		13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:11:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:48:46
User entered 'Day 4 (Day 4)'	Jie Ho (b) (4)	16 Nov 2020 16:52:56
	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '12 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '93'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '100.1' F	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:12:13

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:48:46
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '13 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '0'		16 Nov 2020 20:54:16

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Form: Symptom Log (5)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '93'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	16 Nov 2020 20:54:16

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '98.2' F	(b) (4), (b) (6)	16 Nov 2020 20:54:16

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'		16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:54:16

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:48:46
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '14 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:02:27
User entered '99'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '98.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:02:27
User entered '97.8' F		16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:57:53

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:48:46
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '15 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '99'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	16 Nov 2020 21:02:27

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '97.8' F	(b) (4), (b) (6)	16 Nov 2020 21:02:27

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		16 Nov 2020 21:02:27

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		16 Nov 2020 21:02:27

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Please add the following per CCGs - if assessment done enter the date of the symptoms and mark assessment not done: Line 9 03Nov2020; line 10 04Nov2020; line 11 05Nov2020; line 12 06Nov2020; line 13 07Nov2020; line 14 08Nov2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 04:37:38
Query 'Please add the following per CCGs - if assessment done enter the date of the symptoms and mark assessment not done: Line 9 03Nov2020; line 10 04Nov2020; line 11 05Nov2020; line 12 06Nov2020; line 13 07Nov2020; line 14 08Nov2020' answered with 'Thank you, updated. Please let me know if this was incorrectly done, we are still awaiting the slide deck from 9/4/2020 from our CRA. ' (Site from CRA).	Jie Ho (b) (4)	17 Nov 2020 03:49:40
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:48:46
User opened query 'Please add the following per CCGs - if assessment done enter the date of the symptoms and mark assessment not done: Line 9 03Nov2020; line 10 04Nov2020; line 11 05Nov2020; line 12 06Nov2020; line 13 07Nov2020; line 14 08Nov2020' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:23:28
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '0'		16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '96'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '98.3' F	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		16 Nov 2020 21:03:04

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 21:03:04

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 1 (Day 1)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '03 Nov 2020'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'I'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered missing code ND - Not Done.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered empty.	System	17 Nov 2020 03:45:11
User entered '%'	System	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered missing code ND - Not Done.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:20
User entered 'None (None)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:45:11
User entered 'Moderate (Moderate)'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:36
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 03:32:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 03:32:33
User entered '04 Nov 2020' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:32:33
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 03:31:18
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '1' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:32:33
User entered '0'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:32:33
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered empty.	System	17 Nov 2020 03:46:24
User entered '%'	System	17 Nov 2020 03:32:33
User entered empty.	System	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:32:33
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:32:33
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:36:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:32:33
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:32:33
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:46:24
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:33:19
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 03:39:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 03:39:02
User entered '05 Sep 2020' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 03:31:18
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '1' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered '0'	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered empty.	System	17 Nov 2020 03:47:16
User entered '%'	System	17 Nov 2020 03:39:02
User entered empty.	System	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:47:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:39:02
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:31:18

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 4 (Day 4)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '06 Nov 2020'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '0'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered missing code ND - Not Done.	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	17 Nov 2020 03:40:54

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered missing code ND - Not Done.	Jie Ho (b) (4)	17 Nov 2020 03:40:54

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'Moderate (Moderate)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:40:54

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 5 (Day 5)'	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '07 Nov 2020'	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'I'	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered empty.	System	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:47:49

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 6 (Day 6)'	Jie Ho (b) (4)	17 Nov 2020 03:48:03

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '08 Nov 2020'	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'I'	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered empty.	System	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered empty.	Jie Ho (b) (4)	17 Nov 2020 03:48:03

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:10:45

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '17 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '98'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '98.3' F		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:10:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '99'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '97.1' F		19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:40:12

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '19 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '0'		20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '99'		20 Nov 2020 13:17:45

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '98.4' F	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:17:45

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 18 (Day 18)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '20 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '98'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '98.5' F		22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:01:50

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 19 (Day 19)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '21 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered '0'		22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered missing code ND - Not Done.		22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered '96.6' F		22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:02:56

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Day 20 (Day 20)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '22 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '98'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered '%'	System	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered '97.9' F	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:35:39

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:30
User entered 'None (None)'		22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:48:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:30
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:35:39

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:36
User closed query 'Per GCL Lab recon: Swab: Sample collection date 09-NOV-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in PPD portal. Kindly confirm if swab sample was collected on 09-NOV-2020 for Covid-19 Assessment visit to be updated in PPD portal records.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:53:41
Query 'Per GCL Lab recon: Swab: Sample collection date 09-NOV-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in PPD portal. Kindly confirm if swab sample was collected on 09-NOV-2020 for Covid-19 Assessment visit to be updated in PPD portal records.' answered with 'Confirming this swab was collected on 11/9/2020.' (Site from DM).	Jie Ho (b) (4)	13 Nov 2020 15:51:57
User opened query 'Per GCL Lab recon: Swab: Sample collection date 09-NOV-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in PPD portal. Kindly confirm if swab sample was collected on 09-NOV-2020 for Covid-19 Assessment visit to be updated in PPD portal records.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:50:58
User entered '09 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 21:20:17

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

[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 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 21:20:17

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

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 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:36
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).		17 Nov 2020 14:51:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 14:51:41
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 'COVID-19 is documented in the AE log.' (Site from System).	Jie Ho (b) (4)	16 Nov 2020 03:22:06
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	13 Nov 2020 15:50:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Jie Ho (b) (4)	13 Nov 2020 15:50:51
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:20:22
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:20:17
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:17

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Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:36
User entered '09 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 21:20:17

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:36
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	09 Nov 2020 21:20:17

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:36
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:17

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

[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 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 21:20:17

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:20:36
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:17

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:36
User entered empty.		09 Nov 2020 21:20:17

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:48:19

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User entered 'I'	System	13 Nov 2020 15:50:51

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:56:14

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

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 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Folder: Covid-19 Assessment 06 Nov 2020

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Generated On: 11 Aug 2021 22:48:19

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Folder: Covid-19 Assessment 06 Nov 2020

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered 'Yes (Y)' reason for change: Data Entry Error		16 Nov 2020 20:52:57
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:57
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:57
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered '93' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:57
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[Mechanical Ventilation?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[End Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:20:42
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).		12 Jan 2021 10:05:00
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' answered with 'updated' (Site from DM).		06 Jan 2021 14:48:50
User entered 'No (N)' reason for change: Data Entry Error		(b) (4), (b) (6) 06 Jan 2021 14:48:45
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).		04 Jan 2021 22:39:15
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[Evidence of Shock Requires
Vasopressors](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
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[Acute Renal Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 14:48:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

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[Date of Assessment](#)

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
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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 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:56:14

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

US3472130

Folder: Covid-19 Assessment 06 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:48:19

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:05
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:20:42
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:56:14

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:48:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:48:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:48:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered '11 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:48:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:48:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:12:25
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:08:41
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:03
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:48:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered '13 Nov 2020' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:12:25
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:48:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:48:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:21:43
User entered 'Yes (Y)' reason for change: Data Entry Error		16 Nov 2020 21:03:24
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:08:41
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:03
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:48:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per ETRTR: Date of Collection for DAY 7 is not 2 days after Date reported for Day 5. Please review and reconcile.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:45:11
	(b) (4), (b) (6)	15 Feb 2021 14:21:43
Query 'Per ETRTR: Date of Collection for DAY 7 is not 2 days after Date reported for Day 5. Please review and reconcile.' answered with 'Transport could not be arranged for 15NOV2020, sample was collected on 16NOV2020.' (Site from CRA).	Jie Ho (b) (4)	07 Dec 2020 20:44:43
User opened query 'Per ETRTR: Date of Collection for DAY 7 is not 2 days after Date reported for Day 5. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	27 Nov 2020 17:52:28
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:03:24
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:48:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:48:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered 'Yes (Y)' reason for change: Data Entry Error		18 Nov 2020 17:09:50
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:08:41
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:03
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:48:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 17:09:50
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:48:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:48:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered 'Yes (Y)' reason for change: Data Entry Error		24 Nov 2020 18:13:01
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:08:41
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:03
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:48:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per ETRTR: Date of Collection for DAY 14 is not 5 days after Date reported for Day 9. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 13:49:25
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:43
Query 'Per ETRTR: Date of Collection for DAY 14 is not 5 days after Date reported for Day 9. Please review and reconcile.' answered with 'Transport of sample could not be arranged for Day 14. Sample was collected on 23NOV2020 as recorded.' (Site from CRA).	Jie Ho (b) (4)	07 Dec 2020 20:46:03
User opened query 'Per ETRTR: Date of Collection for DAY 14 is not 5 days after Date reported for Day 9. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	27 Nov 2020 17:55:15
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:13:01
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:48:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:48:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered 'Yes (Y)' reason for change: Data Entry Error		01 Dec 2020 18:36:34
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:08:41
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:03
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:48:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:36:34
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:48:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:48:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:21:43
User entered 'Yes (Y)' reason for change: Data Entry Error		07 Dec 2020 19:41:22
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:08:41
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:08:03
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:48:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:43
User entered '07 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:41:22
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:08:03

US3472130

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:00
User closed query 'Please reconcile and enter saliva log as required' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:38:03
Query 'Please reconcile and enter saliva log as required' answered with 'Saliva log updated.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:15:08
User opened query 'Please reconcile and enter saliva log as required' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:44:09
User entered 'Yes (Y)'		09 Nov 2020 21:20:41

US3472130

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:00
User entered '09 Nov 2020'		09 Nov 2020 21:20:41

US3472130

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[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 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:21:00
User entered 'Home (Home)'	(b) (4), (b) (6)	09 Nov 2020 21:20:41

US3472130

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	09 Nov 2020 21:20:41

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:05
User entered 'Yes (Y)'		09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 15 Feb 2021 14:21:05
User entered '09 Nov 2020'		09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:21:05
User entered '12:02'	(b) (4), (b) (6)	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User entered '09 Nov 2020 12:02'	System	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:05
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:26:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 21:26:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:26:41
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:20:58
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:58
DataPoint set to visible.	System	09 Nov 2020 21:20:41

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:05
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:26:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 21:26:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:26:41
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:20:58
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:58
DataPoint set to visible.	System	09 Nov 2020 21:20:41

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:05
User entered '99' F		09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:05
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:21:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Nov 2020 21:21:36
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:21:36
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:20:58
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	15 Feb 2021 14:21:05
User entered empty.		09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:05
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:21:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 21:21:36
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:21:36
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:20:58
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Nov 2020 21:21:36
User entered empty.	System	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:05
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:21:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 21:21:36
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:21:36
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:20:58
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Nov 2020 21:21:36
User entered empty.	System	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:05
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 13:16:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:26:41
Query 'Data is required. Please provide.' answered with 'Could not obtain - deviation filed' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:21:29
User opened query 'Data is required. Please provide.' System (Site from System).		09 Nov 2020 21:20:58
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 21:26:41
User entered empty.	System	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:05
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 13:16:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:26:41
Query 'Data is required. Please provide.' answered with 'Could not obtain - deviation filed' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:21:31
User opened query 'Data is required. Please provide.' System (Site from System).		09 Nov 2020 21:20:58
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 21:26:41
User entered empty.	System	09 Nov 2020 21:20:58

US3472130

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:10
User entered 'Yes (Y)'		09 Nov 2020 21:27:10

US3472130

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:21:10
User entered '09 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 21:27:10

US3472130

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:48:19

[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 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:15
User entered 'Yes (Y)'		09 Nov 2020 21:27:18

US3472130

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:48:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:21:15
User entered '09 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 21:27:18

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:22
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "07DEC2020 swab sample in EDC under saliva collection"; however, per PPD portal, on 07-DEC-2020, swab sample was collected and the same is missing in EDC. Kindly consider updating EDC for swab sample collected on 07-DEC-2020 by initiating Covid-19 assessment eCRF for the corresponding date and updating swab data in Covid Diagnostic Test eCRF, as we do not have provision to capture swab samples on Convalescent eCRF, else clarify in site response, if saliva or swab was collected on 07-DEC-2020.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 07:36:18
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "07DEC2020 swab sample in EDC under saliva collection"; however, per PPD portal, on 07-DEC-2020, swab sample was collected and the same is missing in EDC. Kindly consider updating EDC for swab sample collected on 07-DEC-2020 by initiating Covid-19 assessment eCRF for the corresponding date and updating swab data in Covid Diagnostic Test eCRF, as we do not have provision to capture swab samples on Convalescent eCRF, else clarify in site response, if saliva or swab was collected on 07-DEC-2020.' answered with 'Previous response was in error, confirmed only saliva sample was collected on 07Dec2020. No swab was collected.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:48:09

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "07DEC2020 swab sample in EDC under saliva collection"; however, per PPD portal, on 07-DEC-2020, swab sample was collected and the same is missing in EDC. Kindly consider updating EDC for swab sample collected on 07-DEC-2020 by initiating Covid-19 assessment eCRF for the corresponding date and updating swab data in Covid Diagnostic Test eCRF, as we do not have provision to capture swab samples on Convalescent eCRF, else clarify in site response, if saliva or swab was collected on 07-DEC-2020.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:26:02
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 07DEC2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:26:02
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 07DEC2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate.' answered with '07DEC2020 swab sample in EDC under saliva collection' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 18:41:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 07DEC2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 18:02:53
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Dec 2020 18:02:42
Reviewed for Data Management.		28 Dec 2020 18:02:38
User entered 'Yes (Y)'		07 Dec 2020 19:41:35

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:21:22
Un-reviewed for Data Management.	(b) (4), (b) (6)	04 Jan 2021 05:25:58
Reviewed for Data Management.		04 Jan 2021 05:25:54
User entered '07 Dec 2020'		07 Dec 2020 19:41:35

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[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 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:22
User entered 'Clinic (Clinic)'		07 Dec 2020 19:41:35

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	07 Dec 2020 19:41:35

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:26
User entered 'Yes (Y)'		07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:26
User entered '07 Dec 2020'		07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:21:26
User entered '14:21'	(b) (4), (b) (6)	07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User entered '07 Dec 2020 14:21'	System	07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:26
User entered missing code ND - Not Done.		07 Dec 2020 19:42:14
DataPoint set to visible.	System	07 Dec 2020 19:41:35

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:21:26
User entered missing code ND - Not Done.	(b) (4), (b) (6)	07 Dec 2020 19:42:14
DataPoint set to visible.	System	07 Dec 2020 19:41:35

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:26
User entered '36.7' C		07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:26
User entered 'Oral (Oral)'		07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:21:26
User entered empty.		07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:26
User entered '88'		07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:21:26
User entered '16'	(b) (4), (b) (6)	07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:26
User entered '136'		07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:26
User entered '84'		07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Dec 2020 19:42:14

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	15 Feb 2021 14:21:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 19:42:24

US3472130

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:31
User entered '07 Dec 2020'		07 Dec 2020 19:42:24

US3472130

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:48:19

[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 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:36
User entered 'Yes (Y)'		07 Dec 2020 19:42:37

US3472130

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:48:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:21:36
User entered '07 Dec 2020'		07 Dec 2020 19:42:37

US3472130

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

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:30:12

US3472130

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

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:30:12

US3472130

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

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[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 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:30:12

US3472130

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

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 14:30:12

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:31:36

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[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 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:45:06

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:31:36

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
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 15:45:06

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:31:36

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:31:36

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:31:36

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:31:36

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:31:36

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered '1'	System	04 Feb 2021 14:31:36

US3472130

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

Form: Unblinding

Generated On: 11 Aug 2021 22:48:19

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'I'	System	04 Feb 2021 14:31:36

US3472130

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered empty.	System	04 Feb 2021 14:35:44
DataPoint set to visible.	System	04 Feb 2021 14:31:36

US3472130

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered empty.	System	04 Feb 2021 14:35:44
DataPoint set to visible.	System	04 Feb 2021 14:31:36

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User accepted default value 'Pre-Dose (PREDOSE)'		04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '13:21'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered '03 Feb 2021 13:21'	System	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '91'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'bpm'	System	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '18'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'breaths/min'	System	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '134'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'mmHg'	System	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '81'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'mmHg'	System	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered empty.	System	04 Feb 2021 14:35:44
DataPoint set to visible.	System	04 Feb 2021 14:31:36

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 15:07:27
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Feb 2021 15:07:27
User entered '14:14' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:07:27
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Feb 2021 14:35:44
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered '03 Feb 2021 14:14'	System	05 Feb 2021 15:07:27
User entered empty.	System	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 15:08:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Feb 2021 15:08:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:08:06
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Feb 2021 14:35:44
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '86'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'bpm'	System	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '16'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'breaths/min'	System	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '138'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'mmHg'	System	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '88'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:35:44

US3472130

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User entered 'mmHg'	System	04 Feb 2021 14:35:44

US3472130

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:36:00

US3472130

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:14
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:36:00

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:36:25

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:36:25

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:36:25

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User entered 'mRNA-1273'	System	04 Feb 2021 14:36:25
DataPoint set to visible.	System	04 Feb 2021 14:31:36

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:36:25

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '13:48'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:36:25

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User entered '03 Feb 2021 13:48'	System	04 Feb 2021 14:36:25

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:36:25

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User entered 'ONCE'	System	04 Feb 2021 14:36:25

US3472130

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

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 14:36:25

US3472130

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:37:15

US3472130

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:37:15

US3472130

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '13:32'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:37:15

US3472130

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User entered '03 Feb 2021 13:32'	System	04 Feb 2021 14:37:15

US3472130

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:48:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:37:28

US3472130

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:48:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:37:28

US3472130

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:48:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '13:34'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:37:28

US3472130

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User entered '03 Feb 2021 13:34'	System	04 Feb 2021 14:37:28

US3472130

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

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:37:32

US3472130

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

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:06
User entered 'I'	System	04 Feb 2021 14:37:32

US3472130

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:34:32

US3472130

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:34:32

US3472130

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:34:32

US3472130

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:34:32

US3472130

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:34:37

US3472130

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:22
User entered 'I'	System	10 Feb 2021 19:34:37

US3472130

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:22
User entered '1'	System	10 Feb 2021 19:34:37
DataPoint set to visible.	System	10 Feb 2021 19:34:37

US3472130

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:17:02

US3472130

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:17:02

US3472130

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[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 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:17:02

US3472130

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'OLD29'	System	05 Mar 2021 16:17:02

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User accepted default value 'Pre-Dose (PREDOSE)'		05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '13:37'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered '4 Mar 2021 13:37'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '85'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'bpm'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'breaths/min'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '129'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'mmHg'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '76'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'mmHg'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '14:14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:08:18
User entered '14:44'		05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered '4 Mar 2021 14:14'	System	11 Mar 2021 16:08:18
User entered '4 Mar 2021 14:44'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '81'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'bpm'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'breaths/min'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '139'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'mmHg'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '84'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'mmHg'	System	05 Mar 2021 16:19:35

US3472130

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:42

US3472130

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:42

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:56

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:56

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:56

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'mRNA-1273'	System	05 Mar 2021 16:19:56
DataPoint set to visible.	System	10 Feb 2021 19:34:37

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:56

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '13:44'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:56

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered '4 Mar 2021 13:44'	System	05 Mar 2021 16:19:56

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:19:56

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'ONCE'	System	05 Mar 2021 16:19:56

US3472130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:48:19

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 16:19:56

US3472130

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:20:01

US3472130

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:25
User entered 'I'	System	05 Mar 2021 16:20:01

US3472130

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:21:27

US3472130

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:21:27

US3472130

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:21:27

US3472130

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:48:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:21:27

US3472130

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:06
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:21:31

US3472130

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:48:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:06
User entered 'I'	System	11 Mar 2021 18:21:31

US3472130

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:31:03

US3472130

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:31:03

US3472130

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[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 19:16:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:31:03

US3472130

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:48:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	05 Apr 2021 20:31:03

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '15:18'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User entered '5 Apr 2021 15:18'	System	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Apr 2021 18:05:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).		06 Apr 2021 18:05:34
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 18:05:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:35:32
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '90'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '139'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '85'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:48:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:35:32

US3472130

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:40

US3472130

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:48:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:40

US3472130

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:57

US3472130

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:57

US3472130

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '15:30'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:35:57

US3472130

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User entered '5 Apr 2021 15:30'	System	05 Apr 2021 20:35:57

US3472130

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:48:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:38:22
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 1; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:36:57
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 1; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated AE log' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:14:01
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:37
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 1; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 16:08:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 21:28:59

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 13:59:37
User entered 'USA-US122-2020-mRNA-1273-P301000002'	System	16 Nov 2020 13:59:32
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 13:59:32

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
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)	13 Nov 2020 18:10:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:10:55
Data point term sent to Coder	System	13 Nov 2020 18:09:38
User entered 'COVID-19'	(b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User closed query 'PV Query: The start date of the event is 03 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 03 Nov 2020 (and any other additional applicable dates) to the Covid-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:21:39
Query 'PV Query: The start date of the event is 03 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 03 Nov 2020 (and any other additional applicable dates) to the Covid-19 assessment symptom log in EDC.' answered with '03NOV2020 is on the symptom log. Assessment was not done that day though since symptoms were not reported until later.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:37:25
User opened query 'PV Query: The start date of the event is 03 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 03 Nov 2020 (and any other additional applicable dates) to the Covid-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:09:32
User entered '03 Nov 2020'		13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 15:12:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4)	30 Nov 2020 21:21:41
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'updated.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 15:12:34
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 15:12:29
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 15:08:55
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
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)	20 Nov 2020 11:00:05
User closed query 'Per CDM: Action taken with IP is 'Investigational Product Withdrawn'; Please complete the Dosing Discontinuation form under End of Study folder. Thank you' (Site from DM).	(b) (4)	20 Nov 2020 09:09:52
Query 'Per CDM: Action taken with IP is 'Investigational Product Withdrawn'; Please complete the Dosing Discontinuation form under End of Study folder. Thank you' answered with 'Completed, thank you.' (Site from DM).	Jie Ho (b) (4)	19 Nov 2020 18:57:59
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 'Should I update this to AE and specify COVID-19 or leave the reason as "due to SARSCOV2"?' (Site from System).	Jie Ho (b) (4)	19 Nov 2020 18:57:49
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	19 Nov 2020 18:56:41
User opened query 'Per CDM: Action taken with IP is 'Investigational Product Withdrawn'; Please complete the Dosing Discontinuation form under End of Study folder. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:25:52
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
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)	30 Nov 2020 21:21:33
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 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 15:12:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 15:12:29
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 15:09:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:12:23
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:48:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 18:08:50

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 20:19:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 20:19:53
Data point term sent to Coder	System	08 Apr 2021 20:18:31
User entered 'injection site redness'	(b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '23:41'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 23:41'	System	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '12:00'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 12:00'	System	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 20:18:24

US3472130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:48:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 20:18:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:48:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:43:45
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	Jie Ho (b) (4)	27 Oct 2020 01:59:55

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Oct 2020 02:01:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 02:01:29
Data point term sent to Coder	System	27 Oct 2020 02:00:47
User entered 'Gabapentin'	Jie Ho (b) (4)	27 Oct 2020 02:00:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Sciatica'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '300'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'mg (mg)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'once daily (QD)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (ORAL)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un May 2013'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
	(b) (4)	
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
	(b) (4)	
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 02:00:24

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 02:02:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 02:02:32
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 02:01:48
User entered 'Bupropion'	Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'depression'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '300'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'mg (mg)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'once daily (QD)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (ORAL)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un Oct 2019'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 02:00:50

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Oct 2020 02:02:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 02:02:34
Data point term sent to Coder	System	27 Oct 2020 02:01:47
User entered 'Zolpidem Tartrate'	Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
	(b) (4)	
User entered 'No (N)'	Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'insomnia'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '10'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'mg (mg)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
	(b) (4)	
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'once daily (QD)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (ORAL)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un Oct 2020'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
	(b) (4)	
User entered empty.	Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 02:01:12

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Oct 2020 02:02:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 02:02:33
Data point term sent to Coder	System	27 Oct 2020 02:01:48
User entered 'Tadalafil'	Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Erectile Dysfunction'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '5'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'mg (mg)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'once daily (QD)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (ORAL)'	Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'un Jun 2020'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 02:01:36

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
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.	(b) (4) Coder Import (b) (4)	27 Oct 2020 02:03:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 02:03:29
Data point term sent to Coder	System	27 Oct 2020 02:02:49
User entered 'flu vaccine'	Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'prophylaxis for influenza'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '1'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Other (OTHER)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'injection'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'once (ONCE)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '05 Oct 2020'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '05 Oct 2020'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 02:02:42

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Dec 2020 20:43:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 20:43:46
Data point term sent to Coder Coding entries removed.	System Jie Ho (b) (4)	07 Dec 2020 20:42:22 07 Dec 2020 20:41:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 16:29:19
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 Nov 2020 16:29:19
Data point term sent to Coder User entered 'Advil'	System (b) (4), (b) (6)	06 Nov 2020 16:28:33 06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:43:35
Query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' answered with 'Updated.' (Site from CRA).	Jie Ho (b) (4)	07 Dec 2020 20:41:52
User entered 'COVID-19' reason for change: Per Query Resolution	Jie Ho (b) (4)	07 Dec 2020 20:41:31
User opened query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' (Site from CRA).	(b) (4), (b) (6)	27 Nov 2020 17:35:21
User entered 'body aches'	(b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:53:37
Query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' answered with 'updated' (Site from DM).		16 Dec 2020 16:46:19
User entered '400' reason for change: Data Entry Error		16 Dec 2020 16:46:13
User opened query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).		15 Dec 2020 07:18:40
User entered '400 mg'		06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 17:48:42
User entered 'Yes (Y)'		06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	17 Dec 2020 17:48:42
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	17 Dec 2020 17:48:33
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 17:48:33
User entered empty.		06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 16:28:22

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED PRESSURE + PAIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Dec 2020 17:33:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:33:37
Data point term sent to Coder	System	07 Dec 2020 20:42:22
Coding entries removed.	Jie Ho (b) (4)	07 Dec 2020 20:42:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED PE SINUS HEADACHE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:15:48
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 18:15:48
Data point term sent to Coder	System	06 Nov 2020 16:30:36
User entered 'Sudafed (325 mg acetaminophen/5mg phenylephrine HCL)'	(b) (4), (b) (6) (b) (4)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:46:27
Query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' answered with 'Updated.' (Site from CRA).	Jie Ho (b) (4)	07 Dec 2020 20:42:36
User entered 'COVID-19' reason for change: Per Query Resolution	Jie Ho (b) (4)	07 Dec 2020 20:42:13
User opened query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' (Site from CRA).	(b) (4), (b) (6)	27 Nov 2020 17:35:47
User entered 'body and headaches'	(b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '2'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '3 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 17:49:42
User entered 'Yes (Y)'		06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 17:49:42
User entered empty.		06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 16:30:29

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
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.	(b) (4) Coder Import (b) (4) (b) (4)	07 Dec 2020 20:43:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 20:43:46
Data point term sent to Coder Coding entries removed.	System Jie Ho (b) (4)	07 Dec 2020 20:43:23 07 Dec 2020 20:42:48
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 Nov 2020 21:49:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:49:44
Data point term sent to Coder User entered 'Ibuprofen'	System (b) (4), (b) (6)	09 Nov 2020 21:41:21 09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:47:33
Query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' answered with 'Updated.' (Site from CRA).	Jie Ho (b) (4)	07 Dec 2020 20:42:53
User entered 'COVID-19' reason for change: Per Query Resolution	Jie Ho (b) (4)	07 Dec 2020 20:42:48
User opened query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' (Site from CRA).	(b) (4), (b) (6)	27 Nov 2020 17:36:15
User entered 'Muscle aches, fever, headache, sore throat'		09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '600'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 17:50:29
User entered 'Yes (Y)'		09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	17 Dec 2020 17:50:29
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:40:51

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
	(b) (4)	
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)	07 Dec 2020 20:43:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:43:46
	(b) (4)	
Data point term sent to Coder	System	07 Dec 2020 20:43:24
Coding entries removed.	Jie Ho (b) (4)	07 Dec 2020 20:43:21
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)	09 Nov 2020 21:41:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:41:38
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 21:41:21
User entered 'Acetaminophen'	(b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User closed query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:48:32
Query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' answered with 'Updated.' (Site from CRA).	Jie Ho (b) (4)	07 Dec 2020 20:43:26
User entered 'COVID-19' reason for change: Per Query Resolution	Jie Ho (b) (4)	07 Dec 2020 20:43:21
User opened query 'Per ETRTR: Medication reported within the time frame of Event "COVID-19", per CRF completion guidelines "If the medication is taken for an adverse event, indicate the verbatim term of the adverse event as reported on the adverse event page". Please consider to update indication.' (Site from CRA).	(b) (4), (b) (6)	27 Nov 2020 17:36:36
User entered 'Fever'	(b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '1000'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 17:50:49
User entered 'Yes (Y)'		09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	17 Dec 2020 17:50:49
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:48:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:41:16

US3472130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:48:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:31:30
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:31:13

US3472130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:48:19

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:34:03

US3472130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:48:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'endoscopy'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:34:03

US3472130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:48:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:34:03

US3472130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:48:19

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:34:03

US3472130

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:48:19

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered '03 Nov 2020'	(b) (4) Jie Ho (b) (4)	19 Nov 2020 18:56:41

US3472130

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:48:19

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
User entered 'Due to SARS-COV-2 (COVID)'	Jie Ho (b) (4)	19 Nov 2020 18:56:41

US3472130

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:48:19

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 19:16:24
User entered empty.	(b) (4) Jie Ho (b) (4)	19 Nov 2020 18:56:41

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered	System	16 Nov 2020 13:59:32
'USA-US122-2020-MRNA-1273-P301000002'		

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:22:07
User entered 'US'	System	16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Dec 2020 19:16:14
User entered '2'	System	30 Nov 2020 21:22:21
User entered '1'	System	16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'USA-US122-2020-MRNA-1273-P301000002'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		30 Nov 2020 21:22:07
User entered 'US'	System	16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Dec 2020 19:16:14
User entered '2'	System	30 Nov 2020 21:22:21
User entered '1'	System	16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:48:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:29:32
User entered '16/Nov/2020 09:00'	System	16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:48:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:22:07
User entered 'I'		16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered	System	16 Nov 2020 13:59:32
'USA-US122-2020-MRNA-1273-P301000002'		

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		30 Nov 2020 21:22:07
User entered 'US'	System	16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Dec 2020 19:16:14
User entered '2'	System	30 Nov 2020 21:22:21
User entered '1'	System	16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:48:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:29:32
User entered '30/Nov/2020 21:22'	System	30 Nov 2020 21:22:21

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:48:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 19:16:04
User entered 'I'		30 Nov 2020 21:22:21

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:59:58
User entered 'USA-US122-2020-MRNA-1273-P301000002'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	31 Mar 2021 13:29:32
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		16 Nov 2020 13:59:58
User entered 'No (N)'	System	16 Nov 2020 13:59:32

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:29:32
Reviewed for Safety.		30 Nov 2020 21:22:07
User entered 'US'	System	16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:48:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Dec 2020 19:16:14
User entered '2'	System	30 Nov 2020 21:22:21
User entered '1'	System	16 Nov 2020 14:00:08

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:48:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:29:32
User entered '02/Dec/2020 19:16'	System	02 Dec 2020 19:16:14

US3472130

Folder: SAE USA-US122-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:48:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:29:32
User entered 'I'		02 Dec 2020 19:16:14